

#### UNIVERSITY OF THESSALY

#### DEPARTMENT OF PHYSICAL EDUCATION AND SPORT SCIENCE

# THE EFFECTIVENESS OF PHYSICAL ACTIVITY INTERVENTIONS IN THE REDUCTION OF DEPRESSIVE SYMPTOMS IN PREGNANT WOMEN AND THE PREVENTION OF POSTNATAL DEPRESSION

by

Natalia Antigoni Tzouma

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Supervisory team:

Comoutos Nikolaos, Associate Professor (Supervisor) Papaioannou Athanasios, Professor Digelidis Nikolaos, Professor

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To my dad.

#### ABSTRACT

This thesis investigated the effectiveness of Physical Activity (PA) interventions in the reduction of depressive symptoms in pregnant women and the prevention of perinatal depression.

Perinatal depression (PD) is affecting approximately 16% of pregnant and 20% of postpartum women. Regular perinatal PA is considered a preventive factor for PD symptoms offering fewer side effects than antidepressants and wider accessibility than psychological treatments.

This thesis consisted of three studies. Fist, a systematic review and meta-analysis synthesizing evidence exclusively from randomized controlled trials (RCTs) examining the effects of exercise on PD symptoms in women recruited via perinatal health services. Exercise showed a statistically significant small overall antidepressant effect (SMD = -.21, 95% CI = -.31, -.11, p= .0001) with low/non-significant heterogeneity (Q = 17.82, I<sup>2</sup> = 16%, p= .27). Subgroup analyses revealed significant antidepressant effects for exercise across various settings, delivery formats, depressive symptoms severities and outcome measures used. Heterogeneity was low/non-significant in all analyses (I  $^2 \leq 50\%$ ).

Second, a two-arm randomized controlled trial to evaluate the effectiveness of an Exercise Counselling (EC) intervention compared to Perinatal Wellbeing Education (PWE) on depressive symptoms, anxiety levels and sleep quality of perinatal individuals recruited via obstetric care practices. The implemented EC intervention was beneficial for alleviating depressive symptoms, as well as decreasing anxiety levels and sleep disturbances. Results suggested that exercise is not automatically related to reduced symptoms of depression and anxiety and that contextual factors associated with exercise parameters and domains (i.e., intensity of PA, domain-specific PA) are probably crucial to such effects. Third, a qualitative study to illustrate perinatal women's views and experiences deriving from an Exercise Counselling (EC) intervention and evaluate the intervention's acceptability. The analysis resulted in three overarching themes. Main obstacles to engagement with the EC intervention, which revealed that sociocultural factors had a major impact on women's participation in the intervention; factors that enabled participation in the EC intervention which showed that obstetricians' reinforcement contributed in perinatal women's decision-making process, and that the affective effect of exercise as well as the ability to regulate the intensity pace attributed to the EC intervention adherence; participants' suggestions to improve the EC intervention, which demonstrated that participants would like the partner involvement and engaging to the EC earlier during the pregnancy.

Findings are clinically useful but more RCTs for clinically diagnosed women with PD and follow-up measurements are needed for firmer conclusions. Additional research is needed to understand how self-paced exercise is related to acute affective responses to exercise and future exercise behaviour among perinatal population.

'I certify that this thesis is my own work, based on my personal study and/or research and that I have acknowledged all material and sources used in its preparation, whether they be books, articles, reports, lecture notes, and any other kind of document, electronic or personal communication'

#### ΠΕΡΙΛΗΨΗ

Η παρούσα διατριβή διερεύνησε την αποτελεσματικότητα των παρεμβάσεων Φυσικής Άσκησης (ΦΑ) στη μείωση των συμπτωμάτων κατάθλιψης σε έγκυες γυναίκες και την πρόληψη της περιγεννητικής κατάθλιψης.

Η Περιγεννητική Κατάθλιψη (ΠΚ) επηρεάζει περίπου το 16% των εγκύων και το 20% των λεχωίδων. Η συστηματική ΦΑ έχει προταθεί ως προστατευτικός παράγοντας για την εμφάνιση συμπτωμάτων ΠΚ απαλλαγμένη από τις παρενέργειες της αντικαταθλιπτικής φαρμακευτικής αγωγής και παρέχοντας ευρύτερη πρόσβαση σε σύγκριση με την ψυχολογικές θεραπείες.

Η παρούσα διατριβή περιλαμβάνει τρείς μελέτες. Μια συστηματική ανασκόπηση και μεταανάλυση συνθέτοντας στοιχεία αποκλειστικά από τυχαιοποιημένες μελέτες, εξετάζοντας την επίδραση της ΦΑ στα συμπτώματα ΠΚ συμμετεχουσών μέσω περιγεννητικών υπηρεσιών υγείας. Η ΦΑ έδειξε στατιστικά σημαντική μικρή επίδραση (SMD = -.21, 95% CI = -.31, -.11, p= .0001) με χαμηλή/ μη στατιστικά σημαντική ετερογένεια (Q = 17.82, I<sup>2</sup> = 16%, p= .27). Οι αναλύσεις των υποομάδων ανέδειξαν σημαντική επίδραση της ΦΑ στα συμπτώματα ΠΚ μεταξύ των διαφόρων χώρων που πραγματοποιούνταν η ΦΑ, των διαφόρων μεθόδων διεξαγωγής της ΦΑ, της βαρύτητας των συμπτωμάτων ΠΚ και των οργάνων μέτρησης των συμπτωμάτων ΠΚ. Η ετερογένεια ήταν χαμηλή/μη στατιστικά σημαντική σε όλες τις αναλύσεις (I<sup>2</sup> ≤ 50%).

Μια δύο σκελών τυχαιοποιημένη μελέτη για τη διερεύνηση της αποτελεσματικότητας μιας Συμβουλευτικής Παρέμβασης ΦΑ (ΣΠΦΑ) σε σύγκριση με τη παροχή Ψυχοεκπαίδευσης με θέμα την περιγεννητική ευεξία στα συμπτώματα ΠΚ, τα επίπεδα άγχους και την ποιότητα ύπνου συμμετεχουσών μέσω μαιευτικών υπηρεσιών υγείας. Η ΣΠΦΑ ήταν αποτελεσματική στη μείωση των συμπτωμάτων ΠΚ, άγχους και δυσκολιών ύπνου. Ωστόσο, τα αποτελέσματα έδειξαν ότι η ΦΑ δεν σχετίζεται αυτόματα με μειωμένα συμπτώματα ΠΚ και άγχους αλλά παράγοντες που σχετίζονται με παραμέτρους της ΦΑ όπως η ένταση και το είδος της ΦΑ παίζουν καθοριστικό ρόλο σε αυτό.

Τέλος, μια ποιοτική μελέτη με στόχο να αναδείξει τις απόψεις και την εμπειρία των συμμετεχουσών στη ΣΠΦΑ και να αξιολογήσει την καταλληλόλητα της παρέμβασης. Η θεματική ανάλυση ανέδειξε τρία κύρια θέματα. Πρώτον, τα βασικά εμπόδια συμμετοχής στη Συμβουλευτική παρέμβαση ΦΑ, όπου κοινωνικοπολιτισμικοί παράγοντες είχαν σημαντική επίδραση στη συμμετοχή ή μη των γυναικών στη ΣΠΦΑ. Δεύτερον, παράγοντες που ενίσχυσαν τη συμμετοχή στη Συμβουλευτική παρέμβασης των γυναικών στη ΣΠΦΑ. Δεύτερον, παράγοντες που ενίσχυσαν τη συμμετοχή στη Συμβουλευτική παρέμβαση ΦΑ, όπου κοινωνικοπολιτισμικοί παράγοντες που ενίσχυσαν τη συμμετοχή στη Συμβουλευτική παρέμβαση ΦΑ, όπου αναδείχθηκε η σημαντικότητα της ενίσχυσης και της θετικής ανατροφοδότησης των μαιευτήρων για τις συμμετέχουσες, η θετική επίδραση της ΦΑ στο συναίσθημα των γυναικών και το ρόλο που έπαιξε στη συστηματική τους συμμετοχή στην ΣΠΦΑ η ικανότητα να ελέγχουν αυτόβουλα το ρυθμό της ΦΑ. Τρίτον, οι προτάσεις των συμμετεχουσών για βελτίωση της παρέμβασης, οι οποίες περιλάμβαναν την συμμετοχή του συντρόφου στη ΣΠΦΑ και την επιθυμία τους για έναρξη της παρέμβασης νωρίτερα κατά την κύηση.

Τα ευρήματα των μελετών αυτής της διατριβής έχουν κλινική σημασία, ωστόσο, περισσότερες τυχαιοποιημένες μελέτες με συμμετέχουσες με διάγνωση ΠΚ καθώς και μελέτες με επαναλαμβανόμενες μετρήσεις απαιτούνται για την εξαγωγή ασφαλών συμπερασμάτων. Η περαιτέρω διερεύνηση της επίδρασης της αυτορρυθμιζόμενης έντασης της ΦΑ στις άμεσες συναισθηματικές αντιδράσεις και τη μελλοντική συμπεριφορά ΦΑ γυναικών κατά την περιγεννητική περίοδο κρίνεται απαραίτητη.

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Table 1. Description of exercise randomized controlled trials for perinatal depressive symptoms.

Trial	Interventions	Number / Age (M±SD)	Attend. / Dropouts^	Concurrent therapies	Depression outcomes
Daley et al. (2008) UK	<u>A. Exercise counselling</u> Individual home-based counselling (TPB) by trained researcher to encourage women perform aerobic exercise activities at moderate intensity (focus: pram-walk) for 30min, 5times/week/12weeks. Pedometers were given. Counselling: i) two 1-hour sessions (week 1 &4), ii) support phone-calls for 10min (week 3 & 9).	20 / 29-31yrs majority	55% 20% (n=4)	65% (n=13) <sup>A</sup> 30% (n=6) <sup>C</sup>	EPDS Baseline severity: moderate-severe
	<u>B. Wait-list group (control group)</u> Advised not to change current exercise patterns. At baseline, informed about their option to attend exercise consultation at the end of the study.	18 / 29-31yrs majority	/ 16% (n=3)	50% (n=9) <sup>A</sup> 50% (n=9) <sup>C</sup>	Baseline severity: moderate- severe
	<u>Inclusion Criteria</u> : age $\geq$ 16, child $\leq$ 12 months' old, EPDS score > 12, absent symptoms, no pregnant at recruitment, physical activity $<$ 30min/3times/week	ce of severe postna the past 3months	atal depression 3.	, psychiatric treat	ment, and psychotic
Forsyth et al. (2017) UK	<u>A. Aerobic exercise &amp; coaching</u> One single, face-to-face, exercise consultation (Behaviour Change approach), in groups, to motivate participants to exercise 150min/week/12weeks in moderate intensity. Structured sessions lasted 60 minutes at intensity 40–65% predicted maximum oxygen consumption (VO2max). Participants could choose among exercise modalities: i) group-based pram-walk ii) facility-based group exercise with free childcare iii) self-initiated home-based exercise.	11 / 25 ± 5.1	1.pram- walk: 14% 2.facility- based exercise: 24% / 0% .		EPDS Baseline severity: moderate-severe
	<u>B. Usual care (control group)</u> Instructed to continue with their usual healthcare programme.	11 / 27 ± 5.5	/ 0%		Baseline severity: moderate-severe

<u>Inclusion Criteria</u>:  $\leq$  6weeks postpartum, EPDS score  $\geq$  12, clinical diagnosis via Structured Clinical Interview (SCID-IV), no severe mental illness, no contradiction to exercise, moderate to vigorous exercise <1hour/week perinatally, resident of Stoke-on-Trent, UK.

Trial	Interventions	Number / Age (M±SD)	Attend. / Dropouts^	Concurrent therapies	Depression outcomes
Perales et al. (2015) Spain	<u>A. Aerobic exercise</u> Aerobic exercise, supervised by fitness specialist, 55-60min/3times/week for 29weeks, in groups (10-12), low to moderate intensity measured with heart rate monitor (55-60% MHRR) adjusted based on ratings on Borg scale. Specifically: 5-8min warm-up (walk), 25min aerobic exercise (dance, major muscle group exercises), 10min balancing exercises, 10min pelvic floor training, 5-8min cool- down. Location: hospital gym, altitude 600m (19-21 °C, humidity 50-60%).	101 / 31.1 ± 3.4	/ 10.8% (n=11)		CES-D Baseline severity: mild
	<u>B. Usual care (control group)</u> Received usual information by midwifes or health care professionals. Women did not exercise during this period.	83 / 31.7 ± 3.9	/ 7.2% (n=6)		Baseline severity: mild
	<u>Inclusion Criteria</u> : $\leq$ 12 weeks gestation, singleton and uncomplicated pregna no participation in another exercise programme, pre-gestation exercise $\leq$ 4tim	ncy, plan to give nes/week.	birth in the stu	dy hospital, receiv	ve medical follow-ups,
Robledo- Colonia et al. (2012) Colombia	<u>A. Aerobic exercise</u> Aerobic exercise classes, supervised by physiotherapist (trained by study personnel) and experienced physician, 60min/3times/week/12weeks, in groups (3- 5), moderate to vigorous intensity (55–75% MHR), monitored with heart rate monitors and adjusted based on ratings on the Borg scale. Specifically: 10min walking, 30min aerobic exercise, 10min stretching and 10min relaxation. Location: hospital gym, spacious, air-conditioned.	40 / 21 ± 3	80.2% / 7.5% (n=3)		CES-D Baseline severity: moderate
	<u>B. Usual care (control group)</u> Usual prenatal care, 1time/week/12weeks. Received no exercise intervention, no attendance of exercise classes, no home-based exercise.	40 / 21 ± 3	/ 7.5% (n=3)		Baseline severity: moderate
	Inclusion Criteria: age 16-30 years old, from 16-20weeks gestation, nulliparo Absence of high blood pressure, chronic medical illnesses, persistent bleeding incompetent cervix, polyhydramnios/oligohydramnios, and miscarriage the p	us, no participation g after 12week, un ast 12months.	on in a structure	ed exercise progra roid disease, plac	amme the past 6months. enta praevia,

Trial	Interventions	Number / Age (M±SD)	Attend./ Dropouts^	Concurrent therapies	Depression outcomes
Vargas- Terrones et al. (2019) Spain follow up	<u>A. Aerobic &amp; strength exercise</u> Aerobic & strength exercise (ACOG guidelines), supervised by fitness specialist, 60min/3times/week/25weeks, in groups (10-12), moderate intensity (55-60% MHRR) adjusted based on the Borg scale and measured with heart-rate monitor. Specifically: 10min warm-up, 25min aerobic exercise, 10min strengthening exercises, 5min coordination & balance, 5-10min cool-down. Location: hospital fitness room. Participants attended usual care doctor's visits at the hospital, 6times/25weeks.	70 / 33.3 ± 2.9	69.3% / 1.4% (n=1)		CES-D Baseline severity: mild
measures were employed	<u>B. Usual care (control group)</u> Attended usual care doctor's visits at the hospital, 6times/25weeks. Advised to follow doctor's general recommendations of nutrition and exercise.	54 / 32.3 ± 5	/ 16% (n=9)		Baseline severity: mild
	<u>Inclusion Criteria</u> : age 18-45, < 14weeks gestation, attend medical follow-up or systemic serious disorders, persistent second or third trimester bleeding, perioduced hypertension, pre-eclampsia, incompetent cervix.	at study hospital, lacenta previa, rup	and none of th otured membrar	e following: card nes, risk of prema	iovascular, respiratory ture labour, pregnancy
Robichaud (2008) USA unpublished Thesis	<u>A. Home-based walking</u> One single, face-to-face, home-based, exercise consultation, by researcher, 45- 60min (Theory of Planned Behaviour), individually, to participate in exercise, 30min/3times/week/6weeks. Received the video cassette, "Walk Away the Pounds Express", guided them to walk with side stepping, backward walking, forward motions, varying arm-movements, and stretches for 3200 meters during each 30min, home-based unsupervised session. Weekly progress encouraged via 10min phone-calls and e-mail check-ups by exercise scientist.	27 / 31.1 ±	98% / 7.4% (n=2)	0% <sup>A</sup>	EPDS Baseline severity: moderate-severe
	<u>B. Wait-list (Control group)</u> Informed at baseline that they could participate in the intervention exercise programme after the post-intervention outcome measurement.	24 30.4 ±	/ 4.1% (n=1)	0% <sup>A</sup>	Baseline severity: moderate-severe
	B. Wait-list (Control group)         Informed at baseline that they could participate in the intervention exercise         programme after the post-intervention outcome measurement.         Inclusion Criteria: age ≥ 20 years old, ≤ 2months postpartum, no medical corr	24 30.4 ±	/ 4.1% (n=1) ychiatric disord	0% <sup>A</sup> lers.	Baseline a moderate

Trial	Interventions	Number / Age (M±SD)	Attend. / Dropouts^	Concurrent therapies	Depression outcomes
Shelton (2015) USA unpublished Thesis	<u>A. Pram-walking</u> Pram-walking Individual or group moderate intensity pram-walking 30min/3times/week/ 6weeks (65%MHR) to complete 3.000steps/session in parks, grounds indoor track/mall (pedometers were given). A researcher sent e-mails 1time/week/6weeks about depression, stress & exercise and phoned to discuss about depression & give feedback on exercise.	3 / 26.7 ± 2.1	/ 0%	0% <sup>A</sup>	EPDS Baseline severity: mild
A 15\$ retail gift card was given upon completion.	<u>B. Education-only (control group)</u> A researcher phoned 1time/week/6weeks to ask about affective states, remind daily step recording and continuation of normal daily activities (pedometers were given). Women were waiting to i) receive info material about depression, stress and ii) exercise at the end of the study.	$3/25 \pm 4.4$	/ 0%	0% <sup>A</sup>	Baseline severity: mild
	absence of pregnancy complications, current self-harm ideation, no current us	se of medication f	or mood disord	ler.	pecial care needs,
Daley et al. (2015) UK Follow up	<u>A. Exercise counselling</u> Individual, home-based counselling (Theory of Planned Behaviour) by facilitator to encourage participants to exercise in moderate intensity (pram-walk & general exercise) for 30min/3-5times/week/24weeks. Home-based counselling: i) two 40- 60min sessions (month 1 & 2), ii) support phone-calls for 15-20min (month 3 & 4). Also, information leaflets were sent via mail to encourage exercise participation (month 3, 4, 5 & 6).	47 / 31.7 ± 5.3	69.4% / 6.3% (n=4)	A 22% (n=10) C 7% (n=3)	EPDS Baseline severity: moderate-severe
measures wee employed	<u>B. Usual care (control group)</u> Received by post the study 'Looking after yourself' about general postnatal self- care at baseline. Exercise was not further encouraged.	47 / 29.3 ± 5.7	/ 10.6% (n=5)	21% (n=10) <sup>A</sup> 21% (n=10) <sup>C</sup>	Baseline severity: moderate-severe

<u>Inclusion Criteria</u>: age  $\geq 18$ ,  $\leq 6$  months postpartum, have a current diagnosis of a major depressive episode (ICD-10), no pregnant at recruitment, no psychotic symptoms, no alcohol or drug dependency, currently inactive.

Trial	Interventions	Number / Age (M±SD)	Attend. / Dropouts^	Concurrent therapies	Depression outcomes
Yang and Chen (2018) Taiwan depression	A. Aerobic & muscle stretching Compact Disc & instructions (based on ACOG guidelines) for individualized home aerobic gymnastic exercise ≥3times/week/3months (15min/session). Exercise included: warm-up, neck, shoulder, arm, chest/breast enhancement, waist, leg, and relax exercise (6min performed in sitting position and 9min in standing position). Digital material was given with instructions to exercise in best possible setting and stop exercise when feel tired	70 / 31.9 ± 4	/ 14.3% (n=10)		EPDS Baseline: mild Mid-intervent.: ↔ Post-intervent.: ↔
was a secondary outcome	<u>B. Usual care (control group)</u> Routine postpartum care only, including postnatal exercise (Kegel exercise, supple spine, tighter abdominals, stronger back, flexible body) through hand-outs and booklets available in obstetric wards.	70 / 32.4 ± 4.1	/ 11.4% (n=8)		Baseline: mild Mid-intervent.: ↔ Post-intervent.: ↔
	Inclusion Criteria: vaginal delivery, no postnatal complications, and informed	l consent to partic	ipate.		
Norman et al. (2010) Australia depression	<u>A. Aerobic &amp; strength training</u> i) Cardiovascular & strength group exercise, supervised by physical therapist, 60min/1time/week/8weeks, moderate intensity (with their babies) in hospital gym. ii) Education sessions by health professionals on mental wellbeing, 30min/1time/week/8weeks. iii) Education material for baby massage, nutrition, sun-care, play development sent via mail 1time/ week/ 8weeks. At week-8, women received a booklet with physical activity resources	80 / 29.3 ± 4	85% / 22.5% (n=18)	0% <sup>A</sup>	EPDS Baseline severity: mild
was a secondary outcome	<u>B. Education only (control group)</u> Educational material about baby massage, nutrition, sun-care, play development sent via mail 1time/week from week-1 to week-8.	81 / 30.1 ± 5.3	/ 9.8% (n=8)	0% <sup>A</sup>	Baseline severity: mild

Inclusion Criteria: from 6weeks-10weeks postpartum, able for regular aerobic exercise, no medication for psychiatric disorder.

Trial	Interventions	Number / Age (M±SD)	Attend. / Dropouts^	Concurrent therapies	Depression outcomes
Haruna et al. (2013) Japan	<u>A. Aerobic exercise</u> Aerobic exercise, supervised by exercise instructors, 90min/4times/week/4weeks, in groups (10 women, with or without their babies). Specifically: 15min warm-up, 50-60min aerobic exercise (bouncing on an exercise ball), 5min rest, 15-20min stretching & cool down. Location: hospital & public health center gym.	50 / 33.8 ± 3.6	88% / 4 % (n=2)		EPDS Baseline severity: mild
depression was secondary outcome	<u>B. Wait-list (Control group)</u> Informed at baseline that they could participate in the intervention exercise programme after the post-intervention outcome measurement.	51 / 33.7 ± 4.0	/ 7.8% (n=4)		Baseline severity: mild
	<u>Inclusion Criteria</u> : age $\geq 20, \leq 2$ months postpartum, absence of medical comp and psychiatric disorders.	lications, restrict	ions for habitua	al physical activit	y participation,
Surkan et al. (2012) USA	<u>A. Healthy lifestyle counselling</u> Individual counselling (Socio-ecologic framework), including 5 home visits in 12months by EFNEP nutrition paraprofessionals and monthly 15min phone calls for 12 months by intervention staff to encourage eating $\geq$ 5 fruit servings/day, $\leq$ 3 red-meat portions/week & exercising 30min/day, $\geq$ 5days/week at moderate-vigorous intensity (pedometers were given). Received usual perinatal care same to control group).	337 / 26.3 ± 6	/ 39.7% (n=134)		CES-D Baseline severity: mild-moderate
	<u>B. Social support (control group)</u> Nutrition risk appropriate assessment and education. Breastfeeding promotion and food vouchers.	342 / 26.7 ± 5.8	/ 41.5% (n=142)		Baseline severity: mild-moderate
	Inclusion Criteria: age 18-44, from 6-20weeks postpartum, eligible for Specia (WIC) and Expanded Food and Nutrition Education Programme (EFNEP), he	I Supplemental Nousehold income	Nutrition Progra	amme for Women poverty level.	, Infants and Children

Trial	Interventions	Number / Age (M±SD)	Attend. / Dropouts^	Concurrent therapies	Depression outcomes
Mohamma- di et al. (2015) Iran	<u>A. Stretching and breathing exercise coaching (prenatal) (1)</u> One 40min educational session on training for exercise during pregnancy, by researcher, in groups. Location: health centre. Participants were given a Compact Disc to perform stretching and breathing exercises for 20-30min/3times/week until delivery, at low intensity, individually, at home.	43 / 25.3 ± 5.2	24%>20 sessions / 11.6 % (n=5)		EPDS Baseline severity: mild
follow up measures were employed for the first intervention group-(a)	<u>B. Stretching &amp; breathing exercise coaching (pre-natal &amp; post-natal) (2)</u> One 40min educational session on training for exercise during pregnancy and postpartum, by researcher, in groups. Location: health centre. Participants were given a Compact Disc to perform stretching and breathing exercises for 20- 30min/3times/week until 2months postpartum, at low intensity, individually, at home. They were instructed to adjust frequency & duration according to their needs during month-1 postpartum.	42 / 25.2 ± 4.7	i) 33% >20 sessions pre-natal ii) 33%: 10-20 sessions post-natal / 14.3% (n=6)		Baseline severity: mild
	<u>C. Usual care (control group)</u> Antenatal and postnatal ordinary educations in a 40min session. Location: Health centre.	42 / 25.5 ± 4.6	/ 14.3% (n=6)		Baseline: mild Post-intervent.: ↔
	Inclusion Criteria: from 26-32weeks gestation, no current depression or other	psychiatric disor	ders, EPDS sco	ore <15, no obstet	rical complications, no

Inclusion Criteria: from 26-32weeks gestation, no current depression or other psychiatric disorders, EPDS score <15, no obstetrical complications, no diseases that could limit exercise, no history of threatened abortion, no placenta previa/signs of preterm labor, no pre-rupture of amniotic membrane in current pregnancy, no participation in regular exercise programme.

Trial Country	Interventions	Number / Age (M±SD)	Attend. / Dropouts^	Concurrent therapies	Depression outcomes		
Huang et al. (2011) Taiwan	<u>A. Physical activity &amp; diet counselling (pre-natal &amp; postnatal) (1)</u> Six one to one counselling sessions for 12 months by master's prepared nurse at scheduled clinic visits with the aim to design an individualized dietary and physical activity education plan. One primary session (30-40min) at 16weeks gestation, five booster sessions (28weeks of gestation, 36-38weeks of gestation, before hospital discharge after a three-seven day stay, 6weeks postpartum, and 3months postpartum). Women also received a researcher-prepared brochure with diet + physical activity information at 16weeks gestation.	80 / 32.1 ± 4.5	/ 23.7 % (n=19)		BDI-II Baseline severity: mild		
depression was a secondary outcome	<u>B. Physical activity &amp; diet counselling (post-natal) (2)</u> Three one to one counselling sessions for 6 months by master's prepared nurse at scheduled clinic visits with the aim to design an individualized dietary and physical activity education plan. One primary session (30-40min) at 24-48hours after giving birth, two booster sessions (6weeks postpartum & 3months postpartum). Women also received a researcher-prepared brochure with diet + physical activity information at 24-48hours after giving birth.	80 / 30.8 ± 3.7	/ 20% (n=16)		Baseline severity: mild		
	<u>C. Usual care (control group)</u> Routine outpatient department obstetric educational programme for pregnant women once each trimester, face-to-face discussions in the health education room with nurse educators about individual concerns, and leaflets on topics related to medical problems, nutrition and exercise during pregnancy.	80 / 31.9 ± 4.8	/ 20% (n=16)		Baseline severity: mild		
	<u>Inclusion Criteria</u> : ≥18 years old, <16weeks of gestation, no cognitive impair participating in another study.	ment or psychiatr	ic illness, able	to speak and read	Chinese, not		
A: Antidepres	: Antidepressants; ACOG: American College of Obstetricians and Gynecologists; BCA: Behaviour Change approach; BDI: Beck Depression						

Inventory; C: Counseling/psychological support; CES-D: Center Epidemiologic Studies Depression scale; EPDS: Edinburg Postnatal Depression

Scale; HR: Heart Rate; MHR: Maximal Heart Rate, MHRR: Maximal Heart Rate Reserve; TBP: Theory Planned Behaviour ---: Not reported.

^: dropout rates at post-intervention.

Table 2. Methodological quality of reviewed trials.

PEDro critorio	Random allocation	Concealed allocation	Baseline balance	Blinding patient/	Dropouts (<15%)	ITT	Statistical comparison	Point and variability	PEDro total score
Trials				assessor			groups	measures	
Perales et al. (2015)									
	1	1	1	0/0/1	1	0	1	1	7
Robledo-Colonia et al. (2012)	1	1	0	0/0/1	1	1	1	1	7
Vargas-Terrones et al. (2019)	1	1	1	0/0/0	1	1	1	1	7
Mohammadi et al. (2015)	1	1	1	0/0/0	0	1	1	1	6
Daley et al. (2015)	1	1	0	0/0/0	1	1	1	1	6
Forsyth et al. (2017)	1	0	0	0/0/1	1	1	1	1	6
Haruna et al. (2013)	1	1	0	0/0/0	1	1	1	1	6
Yang and Chen (2018)	1	0	1	0/0/1	1	0	1	1	6
Norman et al. (2010)	1	1	0	0/0/0	0	1	1	1	5
Daley et al. (2008)	1	0	1	0/0/0	0	1	1	1	5
Huang et al. (2011)	1	0	1	0/0/1	0	0	1	1	5
Robichaud (2008)	1	0	0	0/0/0	1	1	1	1	5
Surkan et al. (2012)	1	0	1	0/0/0	0	1	1	1	5
Shelton (2015)	1	0	1	0/0/0	0	0	1	0	3

PEDro, Physiotherapy Evidence Database Scale; ITT, intention to treat; 0, No; 1, Yes.

Table 3. Meta-analytic findings of the effect of exercise on perinatal depressive symptoms; overall effect and sensitivity analyses

Trial/Arms		Tre	atment Effectivenes	s I	Heterogeneity
		SMD	CI 95%	p value	$I^2$
Overall effect <sup>a-p</sup>	14/16	21	31,11	.0001	16% <sup>NS</sup>
PEDro score of $\geq 6$ a, c, d, g, h, j, l, o, p	8/9	24	43,04	.02	46% <sup>NS</sup>
Controls without exercise conditions <sup>a, c, g - j, l, n</sup>	7/8	28	45,10	.002	41% <sup>NS</sup>
Aerobic exercise at moderate intensity					
for $\geq 150$ min/week <sup>b, c, j, l, o</sup>	5/5	43	64,21	.0002	18% <sup>NS</sup>

SMD: Standardized mean difference; CI 95%: Confidence intervals; NS: Non-significant (p > .05); PEDro:

Physiotherapy of evidence database scale.

<sup>a</sup>Daley et al. (2015b); <sup>b</sup>Daley et al. (2008); <sup>c</sup>Forsyth et al. (2017); <sup>d</sup>Haruna et al. (2013); <sup>e</sup>Huang et al. (2011-a); <sup>f</sup>Huang et al. (2011-b); <sup>g</sup>Mohammadi et al. (2015-a); <sup>h</sup>Mohammadi et al. (2015-b); <sup>i</sup>Norman (2010); <sup>j</sup>Perales (2013); <sup>k</sup>Robichaud, (2008); <sup>l</sup>Robledo-Colognia et al. (2012); <sup>m</sup>Shelton, (2015); <sup>n</sup>Surkan et al. (2012); <sup>o</sup>Vargas-Terrones et al. (2012); <sup>p</sup>Yang & Chen, (2018).

Tria	Trial/Arms		Treatment Effectiveness		Heterogeneiry	
		SMD	CI 95%	p value	$I^2$	
Participants						
Mild-moderate <sup>d</sup> - j, m - p	9/11	17	27,07	.001	0%	
Moderate-severe <sup>a - c, k, 1</sup>	5/5	41	69,13	.005	19% <sup>NS</sup>	
Sedentary/insufficiently inactive at baseline <sup>a - c, j, 1</sup>	5/5	48 *	68,27	.00001	0%	
Unidentified physical activity at baseline <sup>d-i, k, m-p</sup>	9/11	13	24,02	.02	0%	
Post-partum at baseline <sup>a-d, f, h, i, k, m, n, p</sup>	11/11	13	25,02	.01	0%	
Pregnant at baseline <sup>e, g, j, l, o</sup>	5/5	36	60,12	.003	49% <sup>NS</sup>	
Intervention						
Group exercise <sup>d, i, j, l, o</sup>	5/5	36	57,15	.0007	37% <sup>NS</sup>	
Individual exercise <sup>a, b, e - h, k, n, p</sup>	7/9	13	25,01	.04	0%	
> 50% attendance <sup>a, b, d, i - 1, o</sup>	8/8	34 *¶	49,19	.00001	9% <sup>NS</sup>	
< 50% attendance <sup>c, g, h</sup>	2/3	00	30, .31	.82	0%	
Outcomes						
§ EPDS a - d, i, k, m	7/7	23	43,03	.02	0%	
CES-D / BDI <sup>e, f, j, l, n, o</sup>	5/6	30	49,12	.001	50% <sup>NS</sup>	
Follow up						
End of intervention <sup>a, c, g, i, o</sup>	5/5	22	42,03	.02	0%	
Follow up <sup>a, c, g, i, o</sup>	5/5	25	44,06	.01	0%	

Table 4. Meta-analytic findings of the effects of exercise on perinatal depressive symptoms; subgroup analyses.

SMD: Standardized mean difference; CI 95%: Confidence intervals; NS: Non-significant (p > .05); \*: Significantly different at p < .05;

\*¶: Significantly different at p = .05; §: After removing non-aerobic trials; EPDS: Edinburg Postpartum Depression

Scale; BDI: BeckDepression Inventory; CED-S: Centre for Epidemiologic Studies Depression scale.

<sup>a</sup>Daley et al. (2015b); <sup>b</sup>Daley et al. (2008); <sup>c</sup>Forsyth et al. (2017); <sup>d</sup>Haruna et al. (2013); <sup>e</sup>Huang et al. (2011-a); <sup>f</sup>Huang et al. (2011-b); <sup>g</sup>Mohammadi et al. (2015-a); <sup>h</sup>Mohammadi et al. (2015-b); <sup>i</sup>Norman (2010); <sup>j</sup>Perales (2013); <sup>k</sup>Robichaud, (2008); <sup>l</sup>Robledo-Colognia et al. (2012); <sup>m</sup>Shelton, (2015); <sup>n</sup>Surkan et al. (2012); <sup>o</sup>Vargas-Terrones et al. (2012); <sup>p</sup>Yang & Chen, (2018). Table 5. Short description of the stages of change.

Stage of change	Description
Precontemplation	People are not physically active and have no intention of making changes towards the new behaviour in the following six months.
Contemplation	People are still not physically active, but they intend to change in the following six months.
Preparation	People are still not physically active, but they intend to take action in the following 30 days.
Action	People are physically active and have been so for less than six months.
Maintenance	People are physically active and have been so for more than six months.

Table 6. The stages of change as applied to physical activity behaviour.

Stage of change	Physical Activity behaviour
Pre-contemplation (not thinking about change)	Discuss or read about benefits of PA. Write or discuss ways inactivity affects your health and life aspects. Write or discuss what physical activities you enjoy and where these can be done. Speak with a professional about the potential benefits of PA. Write down or discuss rewards for reaching goals. Re-assess stage of change periodically.
Contemplation (thinking about change)	Discuss risks for not changing and benefits of changing (pros/cons). Explore places for PA in the community. Discuss or read about barriers to PA and potential solutions. Make small incremental changes in daily routines. Keep a log of activity and inactivity for a week. Re-assess stage of change periodically.
Preparation (doing some PA)	Check activity log and plan to replace 15min of inactive time each day with a physical activity. Write down enjoyable activities and find friends/colleagues with similarities. Write down rewards for meeting goals. Re-assess stage of change periodically
Action (doing enough PA)	<ul> <li>Write down ways to be physically active each day.</li> <li>Commit yourself to doing 30min of PA each day.</li> <li>Try a new activity you think you might enjoy.</li> <li>Plan to participate in an activity in your community.</li> <li>Write down or discuss ways to remind yourself to be more active during the week.</li> <li>Reflect on the benefits you have already received from being physically active and what further benefits you expect. Re-assess stage of change periodically</li> </ul>
Maintenance (making PA a habit)	Discuss or write down the strategies that have helped you so far and think ways to make these strategies part of your daily routine. Create a PA contract and continue setting short and long-term goals for PA. Discuss what to do if you are not meeting your goals; create a plan; share with others. Find ways to make/maintain PA enjoyable. Re-assess stage of change periodically.

PA = Physical Activity

## Table 7. Processes of change

Stage of change	Catalysts
Precontemplation	Conscious raising Environmental re-evaluation Dramatic relief
Contemplation	Self-re-evaluation Social liberation Dramatic relief Environmental re-evaluation Conscious raising
Preparation	Self-liberation Self-re-evaluation Counter-conditioning Helping relationships
Action	Counter-conditioning Stimulus control Reinforcement management Helping relationships Self-liberation
Maintenance	Helping relationships Environmental re-evaluation Self-liberation Reinforcement management Stimulus control

Table 8. Participants' demographics and perinatal characteristics.

Characteristic	S		
	Intervention (N = 12)	Active Control (N = 13)	p-value
Age (yrs) Median (IQR)	32.5 (5.5)	32 (10.5)	.85
Height (cm) Median (IQR)	167 (8.75)	168 (9)	.78
Weight (kg) at 26weeks gestation Median (IQR)	72.5 (14.5)	70 (17)	.62
Marital status N (%) Married Single	12 (100) 0 (0)	13 (100) 0 (0)	1
<b>Parity</b> N (%) Nulliparous Multiparous	8 (66.7) 4 (33.3)	9 (69.2) 4 (30.8)	1
Education level N (%) University High school/College	10 (83.3) 2 (16.7)	10 (76.9) 3 (23.1)	1
Work status N (%) Employed/Self-employed Unemployed/Maternal leave	6 (50) 6 (50)	7 (53.8) 6 (46.2)	1
Ethnicity N (%) Greek Other	12 (100) 0 (0)	13 (100) 0 (0)	1
Experiencing long term illness N (%) No Yes	12 (100) 0 (0)	13 (100) 0 (0)	1
Prescribed antidepressants N (%) No Yes	12 (100) 0 (0)	12 (100) 0 (0)	1
IVF in current pregnancy N (%) No Yes	10 (83.3) 2 (16.7)	10 (76.9) 3 (23.1)	1

Smoking habits N (%)			
Non-smoker	5 (41.7)	7 (53.8)	.84
Recent cessation	7 (58.3)	6 (46.2)	
Delivery week Median (IQR)	38 (2)	38 (1.5)	.43
<b>Delivery type</b> N (%)			
Vaginal (normal/instrumental)	7 (63.6)	6 (50)	.68
Caesarean (elective/emergency)	4 (36.4)	6 (50)	
<b>Breastfeeding infant</b> N (%)			
No	3 (27.3)	6 (50)	.4
Yes	8 (72.7)	6 (50)	
Smoking at 8weeks post-delivery N (%)			
No	10 (90.9)	9 (75)	.59
Yes	1 (9.1)	3 (25)	
Weight at 8weeks post-delivery (kg) Median (IQR)	70.45 (8.5)	72 (7.75)	.37

IVF = In Vitro Fertilization; IQR= Interquartile Range

Table 9. Outcome measures at pre-intervention.

Outcome measure	<b>Intervention</b> (N = 12)	Active Control (N = 13)	n-value
[range of possible scores]	Median (IQR)	Median (IQR)	p-value
<b>EPDS</b> [0-30]	7 (2.75)	6 (3)	.36
<b>BDI-II</b> [0-63]	8.5 (2)	8 (2.5)	.74
<b>STAI</b> [20-80]			
State anxiety	34.5 (9.5)	29 (7)	.56
Trait anxiety	36.5 (12)	32 (9.5)	.76
<b>PSQI</b> [0-21]	6 (3.25)	6 (2)	.98
Social Desirability [0-13]	4.9 (.78)	4.6 (1)	.39
GT3X+			
Steps/day	6286 (2268)	6307 (3240)	.51
Total intensity PA MET-min/day	279.9 (43.33)	269.6 (127.7)	.83
Low intensity PA MET-min/day	253.3 (31.2)	245.5 (112.5)	.96
Moderate intensity PA MET-min/day	22.1 (13.2)	24 (24.6)	.91
Stage of Change N (%)			
Precontemplation	0 (0)	0 (0)	
Contemplation	5 (41.7)	5 (38.5)	
Preparation	2 (15.4)	2 (15.4)	
Action	3 (25)	3 (23.1)	
Maintenance	2 (16.7)	3 (23.1)	

Table 10. Between and within group comparisons.

Outcome measure	Time point	Intervention (N=12) Median (IQR)	Active Control (N=13) Median (IQR)	p-value <sup>b</sup>	Effect size (between groups)
	Pre-intervention	7 (2.75)	6 (3)	.36	
EPDS	Mid-intervention	4 (1)	7 (1)	<.0001	85
	Post-intervention	2 (2.75)	7 (1.04)	<.0001	85
	p-value <sup>a</sup>	<.0001 *	.15		
	Effect size (within groups)	.86	.15		
	Pre-intervention	8.5 (2)	8 (2.5)	.74	
	Mid-intervention	6 (.8)	9 (1.04)	<.0001	85
BDI-II	Post-intervention	3 (1.75)	8 (1.04)	<.0001	86
DDI-II	p-value <sup>a</sup>	<.0001 * ^	.056		
	Effect size (within groups)	.95	.22		
	Pre-intervention	34.5 (9.5)	29 (7)	.56	
	Mid-intervention	22.5 (3)	26 (5.5)	.014	49
STAI	Post-intervention	25.5 (3.75)	33.67 (12)	.004	58
State anxiety	p-value <sup>a</sup>	.007 ∫	.001 ^ ʃ		
	Effect size (within groups)	.41	.57		
	Pre-intervention	36.5 (12)	32 (9.5)	.76	
	Mid-intervention	25.91 (7.25)	34.67 (9)	.003	59
STAI	Post-intervention	27.18 (5.75)	35.42 (10.5)	.005	56
Trait anxiety	p-value <sup>a</sup>	.014 ∫	.98		
	Effect size (within groups)	.35	.002		
	Pre-intervention	6 (3.25)	6 (2)	.98	
	Mid-intervention	4 (3.75)	5.83 (2)	.02	47
PSOI	Post-intervention	3.14 (1)	4 (.5)	.13	3
	p-value <sup>a</sup>	.004 *	.002 *		
	Effect size (within groups)	.46	.48		

	<b>Pre-intervention</b>	1111 (900)	1200 (480)	.49	
	Mid-intervention	930 (780)	1320 (900)	.17	31
APAQ	Post-intervention	900 (405)	1200 (540)	.1	29
caregiving exercise	p-value <sup>a</sup>	.21	.16		
	Effect size (within groups)	.13	.15		
	Pre-intervention	660 (2385)	1200 (2460)	.75	
	Mid-intervention	0 (0)	0 (0)	.3	20
APAQ	Post-intervention	0 (0)	0 (0)	1	12
exercise	p-value <sup>a</sup>	.001	.003		
	Effect size (within groups)	.56	.48		
	Pre-intervention	330 (255)	300 (150)	.824	
	Mid-intervention	420 (225)	180 (120)	<.0001	72
APAQ Recreational exercise	Post-intervention	270 (105)	240 (120)	.027	45
	p-value <sup>a</sup>	.008 ^	.003 * ∫		
	Effect size	.4	.49		
	(within groups)				
GT3X+ Total PA (min/day)	Pre-intervention	279.9 (43.33)	269.6 (127.7)	.828	
	Mid-intervention	299.73 (90.44)	284.21 (62.03)	.301	40
	Post-intervention	280.46 (30.29)	295 (49.5)	.301	17
	p-value <sup>a</sup>	.076	.558		
	Effect size (within groups)	.22	.05		
	Pre-intervention	6286 (2268)	6307 (3240)	.51	
	Mid-intervention	7545 (1971)	5282 (1693)	.002	63
GT3X+	Post-intervention	7062 (4117)	5666 (870)	.157	28
Steps/day	p-value <sup>a</sup>	.47	.73		
	Effect size (within groups)	.06	.02		

Table 10 continued

	Pre-intervention	253.3 (31.2)	245.5 (112.5)	.96	
GT3X+	Mid-intervention	263.13 (89.05)	272.57 (69.63)	.624	1
Low intensity	Post-intervention	242.19 (51.77)	275.88 (53.72)	.05	39
exercise (min/day)	p-value <sup>a</sup>	.56	.37		
	Effect size	.05	.08		
	(within groups)				
	Pre-intervention	22.1 (13.2)	24 (24.6)	.91	
GT3X+	Mid-intervention	35.98 (16.2)	11.61 (5.13)	<.0001	78
Moderate intensity	Post-intervention	33.5 (27.37)	18.77 (13.82)	.013	5
exercise (min/day)	p-value <sup>a</sup>	.12	.09		
	Effect size	.17	.18		
	(within groups)				

 $PA = Physical Activity; * = statistically significant difference between pre- and post-intervention; <math>\int = statistically significant$ 

difference between pre- and mid-intervention; ^ = statistically significant difference between mid- and post-intervention; <sup>a</sup> = within

groups; <sup>b</sup> = between groups

Table 11. Participants' characteristics.

Characteristic	N (%)
Parity	
Primiparous	5 (62.5)
Multiparous	3 (37.5)
Work status	
Employed/self-employed	4 (50)
Unemployed	4 (50)
Educational qualification	
University degree	8 (100)
Self-reported pre-pregnancy exercise	
Physically active (>150min/week)	2 (25)
Not physically active (<150min/week)	6 (75)
Concurrent medication (during pregnancy)	
Progesterone	1 (12.5)
Acetylsalicylic acid	2 (25)
None	5 (62.5)
Supplementation (during pregnancy)	
Iron	6 (75)
Folic acid	4 (50)
Vitamin D	1 (12.5)
Smoking habits	
Non-smoker	3 (37.5)

Cessation in pregnancy	5 (62.5)
Postpartum restart	1 (20)
IVF in pregnancy	
Yes	2 (25)
No	6 (75)
Concurrent therapies (perinatally)	
Nutritional therapy	2 (25)
None	6 (75)
Type of delivery	
Vaginal	4 (50)
Caesarean non-elective	2 (25)
Caesarean elective	2 (25)
Currently breastfeeding	
Yes	6 (75)
No	2 (25)

#### Table 12. Outcome measures.

Outcome measure	<b>Pre-intervention</b>	36weeks of pregnancy	10weeks postpartum
		Mean (SD)	
BMI	28.1 (4)	29.5 (4.1)	26.8 (4.1)
EPDS score	7.2 (1.2)	4.5 (0.7)	2.6 (1.7)
Average low intensity Exercise (minutes/day)	250 (32.1)	245 (59.1)	248 (29.9)
Average moderate intensity Exercise (minutes/day)	23 (10.5)	37 (9.7)	30 (18.6)

BMI = Body Mass Index; EPDS = Edinburgh Postnatal Depression Scale; IVF = In Vitro Fertilization; SD = Standard Deviation

#### LIST OF FIGURES

Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram.



Figure 2. Forest Plot for the overall effect of exercise on perinatal depression.

	Inte	erventio	n		Control			Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
1.1.1 ALLstudies									
Shelton (2015)	3	1	3	8	6	3	0.3%	-0.93 [-2.77, 0.91]	•
Robledo-Colonia et al. (2012)	10	б	40	16	8	35	4.3%	-0.85 [-1.32, -0.37]	←
Perales et al. (2015)	7.67	6.3	90	11.34	9.74	77	8.9%	-0.45 [-0.76, -0.14]	<b></b>
Daley et al. (2015b)	12.51	5.46	47	14.67	4.86	42	5.3%	-0.41 [-0.83, 0.01]	
Huang et al. (2011-a)	17.59	8.44	61	20.3	8.2	64	7.1%	-0.32 [-0.68, 0.03]	
Vargas-Terrones et al. (2019)	9.94	7.398	70	12.09	10.113	54	7.0%	-0.25 [-0.60, 0.11]	
Norman et al. (2010)	5.47	5.11	80	6.75	5.51	73	8.4%	-0.24 [-0.56, 0.08]	
Daley et al. (2008)	13.1	5.2	20	14.3	5.4	18	2.5%	-0.22 [-0.86, 0.42]	
Forsyth et al. (2017)	11.8	6.1	11	12.7	4.2	11	1.5%	-0.17 [-1.00, 0.67]	•
Surkan et al. (2012)	13.3	12.76	337	15.3	12.76	342	22.2%	-0.16 [-0.31, -0.01]	
Haruna et al. (2013)	3.6	4.2	50	4.1	3.4	51	6.0%	-0.13 [-0.52, 0.26]	
Robichaud (2008)	18.08	3.28	27	18.39	3.68	24	3.3%	-0.09 [-0.64, 0.46]	
Huang et al. (2011-b)	19.95	9.23	64	20.3	8.2	64	7.3%	-0.04 [-0.39, 0.31]	
Mohammadi et al. (2015-b)	6.58	4.63	36	6.5	5.12	36	4.5%	0.02 [-0.45, 0.48]	
Mohammadi et al. (2015-a)	7.66	5.46	38	7.46	4.5	35	4.5%	0.04 [-0.42, 0.50]	
Yang & Chen (2008)	7.6	4.71	60	7.18	4.54	62	7.0%	0.09 [-0.26, 0.45]	
Subtotal (95% CI)			1034			991	100.0%	-0.21 [-0.31, -0.11]	◆
Heterogeneity: Tau <sup>2</sup> = 0.01; Ch	i <sup>2</sup> = 17.8	32, df =	15 (P =	= 0.27);	$ ^2 = 16\%$				
Test for overall effect: Z = 3.96	(P < 0.0	001)							

-0.5 -0.25 0 0.25 0.5 Favours exercise Favours control Figure 3. Funnel Plot for 14 trials /16 comparisons.



SE: Standard error; SMD; Standardized mean difference

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Figure 4. Flow chart of study participants.



Figure 1. Thematic map of super-ordinate and sub-ordinate themes.



## PUBLICATIONS

- Morres, I. D., Tzouma, N. A., Hatzigeorgiadis, A., Krommidas, Ch., Kotronis, K. V., Dafopoulos K., Theodorakis Y., Comoutos N. (in press). Exercise For Perinatal Depressive Symptoms: A Systematic Review and Meta-Analysis of Randomized Controlled Trials in Perinatal Health Services. *Journal of Affective Disorders*. IF (2021): 4.839
- Tzouma, N. A., Morres, I. D., Goudas, M., Krommidas, Ch., Kotronis, K. V., Papaioannou, A., Theodorakis Y., Comoutos N. (in press). Women's Views and Experiences of a Perinatal Exercise Counselling Intervention: A Qualitative Study. *International Journal of Sports and Exercise Psychology*.

IF (2020): 3.304

 Tzouma, N. A., Morres, I. D., Comoutos N., Krommidas, Ch., Kotronis, K. V., Papaioannou, A., Theodorakis Y. (2021). Preliminary results of a randomised control trial for effectiveness of a perinatal exercise counselling intervention on depressive symptoms [Manuscript submitted for publication].

## PRESENTATIONS

- Tzouma, N., Morres, I., Goudas, M., Krommidas, Ch., Kotronis, K., Papaioannou, A., Theodorakis, Y., Comoutos, N. (2021). Women's Views and Experiences of a Perinatal Exercise Counselling Intervention. *International Journal of Sport and exercise Psychology 19*, 509-510. https://doi.org/10.1080/1612197X.2021.1982479
- Tzouma, N., Morres, I., Comoutos, N., Krommidas, Ch., Kotronis, K., Papaioannou, A., Theodorakis, Y. (2021). *Effectiveness of a perinatal Exercise Counselling intervention on alleviating depressive symptoms: Preliminary results of a randomised control trial*. Στα Πρακτικά του 1ου Διεπιστημονικού Συνεδρίου της Ελληνικής Εταιρίας Σεξολογίας και Διαφυλικών Σχέσεων. Αθήνα, Ελλάδα.

# LIST OF ABBREVIATIONS

ACOG: American College of Obstetricians and Gynaecologists **ACTH:** Adrenocorticotropic Hormone **APAQ:** The Athens Physical Activity Questionnaire **ASCM:** American College of Sports Medicine **BDI-II:** Beck Depression Inventory II BMI: Body Mass Index bpm: Beats per Minute **CBG:** Corticosterone Binding Globulin **CBT:** Cognitive-behavioural therapy **CDC:** Centre for Disease Control and Prevention's **CI:** Confidence interval **CRH:** Corticotropin-Releasing Hormone dL: Decilitre DSM-IV: Diagnostic and Statistical Manual of Mental Disorders, 4th edition **DSM-V:** Diagnostic and Statistical Manual of Mental Disorders, 5th edition **EC:** Exercise Counselling **EPDS:** Edinburgh Postnatal Depression Scale gr: Grammars HPA: Hypothalamic-Pituitary-Adrenocortical **ICD-10:** International Classification of Diseases, 10th revision **IRB:** Institutional Review Board **IPT:** Interpersonal Therapy **IPV:** Intimate Partner Violence **IQR:** Interquartile Range **IVF:** In Vitro Fertilization **LE:** Low Intensity Exercise LME: Low to Moderate Exercise

ME: Moderate Intensity Exercise **MET:** Metabolic Equivalent mg: Milligrams MVPA: Moderate to Vigorous Physical Activity NICE: National Institute for Health and Care Excellence NVDRS: National Violent Death Reporting System **OD:** Odds Ratio **PA:** Physical Activity **PD:** Perinatal Depression PHQ-9: Patient Health Questionnaire-9 PMDD: Premenstrual Dysphoric Disorder **PPHN:** Persistent Pulmonary Hypertension of the Neonate **PSQI:** Pittsburgh Sleep Quality Index **PWE:** Perinatal Wellbeing Education **RCT:** Randomised Controlled Trial **SD:** Standard Deviation **SMD:** Standard Mean Difference SoC: Stage of Change **SSRIs:** Selective Serotonin Reuptake Inhibitors **STAI:** State-Trait Anxiety Inventory **TTM:** Transtheoretical Model **VE:** Vigorous Exercise vs: Versus WHO: World Health Organization WIC: Women, Infants, and Children

## **CHAPTER I. INTRODUCTION**

#### **RATIONALE AND PURPOSE**

Perinatal depression (PD) has been identified as a public health problem, affecting approximately 16% of pregnant and 20% of postpartum women with short- and long-term adverse effects for the individual and the whole family (WHO, 2017).

Suggested treatment options for PD include pharmacotherapy and psychological interventions (Sockol et al., 2013). However, stigma, poor healthcare experiences (Hadfield & Wittkowski 2017; Megnin-Viggars et al., 2015), and lack of childcare can affect women's access and compliance to psychological therapies (Goodman, 2009; O'Mahen & Flynn 2008). Also, women often seem to be reluctant to continue or initiate antidepressant medication stating fears of potential adverse outcomes on the infant (Dennis & Chung-Lee, 2006; Misri et al., 2010; Turner et al., 2008). Thus, PD remains widely underdiagnosed and/ or untreated.

The beneficial effect of Physical Activity (PA) during the perinatal period is widely acknowledged and current guidelines suggest that pregnant and postpartum women should engage in at least 150min of moderate-intensity aerobic PA throughout the week (WHO, 2020). PA during the perinatal period is considered a preventive factor for postpartum depressive disorders (ACOG, 2020). On the other hand, being sedentary has been associated with worse mood, increased risk of depression and somatic symptoms that can interfere with social and daily activities (Poudevigne & O'Connor, 2006).

Recent meta-analytic evidence suggested that exercise and PA-based interventions can be effective in preventing and treating depressive symptoms in pregnant (e.g., Daley et al., 2015) and postpartum women (e.g., McCurdy et al., 2017; Poyatos-León et al., 2017).

However, i) previous studies allocated both RCTs and quasi-RCTs (McCurdy et al., 2017; Poyatos-León et al., 2017) ii) results demonstrated wide confidence intervals and high or significant heterogeneity (Daley et al., 2015; Nakamura et al., 2019), iii) trials with both mindful activities (e.g., yoga) and exercise interventions were included (Carter et al., 2019; Davenport et al., 2018), iv) one meta-analysis has been focused only on trials with interventions held during pregnancy (Daley et al., 2015) and two meta-analyses have included exclusively trials with postnatal participants (McCurdy et al., 2017; Carter et al., 2018).

Also, heterogeneity in PA assessment in RCTs, suggests the existence of potential moderators (e.g., PA intensity, PA frequency, PA type) and assessment of PA exclusively with self-reported measures could have threatened validity and reliability of research findings and therefore health-related recommendations.

Furthermore, among RCTs delivering PA-based interventions, only a few of them implemented PA counselling interventions (Daley et al., 2008; Daley et al., 2015; Forsyth et al., 2017; Huang et al., 2011; Lewis et al., 2014; Mohammadi et al., 2015; Surkan et al., 2012) and only three trials delivered theory-based PA counselling interventions (Daley et al., 2008; Daley et al., 2015; Lewis et al., 2014) targeting behaviour change.

Finally, studies exploring participants' experiences and views on the feasibility and acceptability of the PA-based interventions for PD is limited. Qualitative methods within trials can optimise interventions and facilitate interpretation and transferability of findings in applied practice (Clement et al., 2018).

The aim of this thesis was to:

1. Provide an overview of the relevant literature on perinatal depression (PD) and perinatal physical activity (PA), offering insight on areas of both consensus and controversy,

identifying knowledge gaps and discuss how the current research could advance knowledge on the topic.

- Implement a systematic review and meta-analysis in order to synthesize evidence from RCTs investigating the effect of PA and exercise-based interventions on PD symptoms among perinatal individuals recruited via obstetric care practices.
- 3. Implement a two-arm RCT in order to evaluate the effectiveness of an Exercise Counselling (EC) intervention (from 27weeks gestation to 10weeks post-birth, based on the Transtheoretical Model (TTM) of change, compared to Perinatal Wellbeing Education (PWE), on reducing the depressive symptoms of perinatal individuals recruited via obstetric care practices.
- 4. Conduct a qualitative study with semi-structured interviews to explore participants' views and experiences deriving from the Exercise Counselling (EC) intervention and evaluate the intervention's acceptability.

The expected impact of this thesis was to contribute towards increasing the evidence with respect to the effectiveness of EC as a potential intervention for dealing with perinatal depressive symptoms. Further, expected impact was to provide insight on the currently undefined optimum dose/type of exercise for PD, contribute to the extraction of potential clinically useful suggestions in the primary prevention of PD and promote the development of applicable and acceptable PA-based interventions for perinatal populations.

Limitations of this research include the small number of RCTs included in the metaanalysis, as only 14 RCTs involving perinatal individuals recruited via perinatal health services were available, of which only two RCTs included clinically diagnosed samples. Moreover, the RCTs' study sample and the fact that participants' recruitment took place exclusively in the regions of Epirus and Thessaly. Thus, the researcher was not able to explore potential differences or confounding factors stemming from residence in small versus large cities. Moreover, due to the small study sample, it was not possible to conduct secondary analysis and explore the effectiveness of exercise counselling among groups experiencing differences in the severity of depressive symptoms. Exploring the views and experience of women experiencing depression with a range of severities and symptoms may be useful to clinicians when considering the feasibility of treatments and interventions for a range of patients.

#### **CHAPTER II**

## LITERATURE REVIEW

## Abstract

The aim of this chapter is to provide an overview of maternal perinatal depression (PD) and perinatal physical activity (PA), offering insight on areas of both consensus and controversy. The definition, diagnostic criteria, screening process, symptomatology, aetiology, and epidemiology of PD are discussed. Various sociodemographic, biological, and obstetrical risk factors of maternal depression are explored. An evidence-based summary of the potential influences of PD on the individual, the mother-infant interaction and bonding, and the child's development is presented. Moreover, the effects of paternal PD are examined. Current treatment options for PD as well as treatment compliance and potential challenges are explored. The underpinning mechanisms by which PA and exercise can enhance psychological health and current literature surrounding the antidepressant effect of PA and exercise on perinatal populations is discussed. Finally, maternal and neonatal benefits of PA and exercise are highlighted and a summary of current exercise guidelines for perinatal individuals is provided.

## MATERNAL PERINATAL DEPRESSION

In the last few years, maternal PD has been identified as a public health problem. The International Marce Society for Perinatal Mental Health (2018) highlighted the need for a universal psychosocial assessment and detection of PD in the field of primary health care. Moreover, United Nations considered maternal mental health as fundamental in achieving Millennium Development Goals (WHO-UNFPA, 2013).

Over half of the cases of PD remain unrecognized or untreated. Underdiagnosis and lack of proper treatment have adverse consequences on the woman, the child, the family, and the entire society (Bauer et al., 2015).

According to the World Health Organization (WHO), the inclusion of emotional and mental health assessment as a routine component of maternal care could have significant clinical and economic benefits (WHO, 2013).

#### Phenomenology of PD

The perinatal period is unique with respect to the significant physiological and psychosocial changes and adjustments, including modifications in individuals' social-status and decision making.

PD includes minor and/or major depressive episodes and is one of the most prevalent disorders during pregnancy and postpartum (Committee on Obstetric Practice, 2015). Symptoms of PD include depressed mood, loss of interest and energy, changes in sleep or eating patterns, lack of concentration, feelings of worthlessness, and recurrent suicidal ideation. However, symptoms such as sleep disturbance, weight change, and loss of energy are common during the perinatal period and should be differentiated from an associated mood disorder. Anxiety or agitation is often experienced and can be expressed with ruminating and obsessional thoughts

about the pregnancy or the foetus (Abramowitz et al., 2010; Bernstein et al., 2008). PD has been associated with a reduction in mother's attentional bias for infant distress (Pearson et al., 2011). Demonstrating a lack of interest in interacting and holding the baby, or feeling detached from the baby -usually accompanied with feelings of guilt- are not uncommon (Beck, 2002; Yonkers et al., 2012).

## Diagnosis of PD

For the diagnosis of PD to be set, symptoms of depressed mood or loss of interest have to be present for a minimum of two weeks, create significant impairment on individual's functioning, and typically require professional treatment. The clinical presentation of PD is often characterized by mood symptoms causing significant distress (Bernstein et al., 2008; Cooper & Murray, 1997). The criteria for Major Depressive Disorder according to the Diagnostic and Statistical Manual of Mental Disorders, 5<sup>th</sup> edition (DSM-V) are presented in Appendix 1.

It is important to notice that depressive symptoms are presented on a continuum of severity, and not all women will fit in diagnostic categories. PD appears to have several distinct trajectories as reported by the International Perinatal Psychiatry Consortium Postpartum Depression: Action Towards Causes and Treatment, which represents 19 institutions in seven countries (PACT, 2015). Specifically, three classes were outlined, with individuals in the first class to have the least severe symptoms with a mean score of 10.5 in the Edinburgh Postnatal Depression Scale (EPDS), followed by those in the second class (mean EPDS score= 14.8) and those in the third class (mean EPDS score= 20.1). The most severe depressive symptoms were significantly linked to poor mood (mean EPDS score= 20.1), increased anxiety, onset of symptoms during pregnancy, obstetric complications, and suicidal ideation. Also, most individuals in the second class (62%) stated that their symptoms were initiated within four weeks

v. 67% in class 1 and 29% in class 3) (PACT, 2015).

Crucial parts of the clinical evaluation are the assessment of psychotic symptoms and the suicidal risk. During postpartum, mood episodes with psychotic features appear to be more common in primiparous women with the risk of recurrence with each subsequent delivery to range between 30% and 50%.

The diagnosis of PD should not be confused with postpartum "baby blues", which is common and characterized by less severe mood disturbance, irritability, fatigue, and anxiety that usually occurs and resolves within two weeks post-delivery.

# **Onset specifiers of PD**

Although PD is a widely researched disorder, controversy exists regarding how to best define the onset of symptoms in the perinatal period (Elliott et al., 2000; Wisner et al., 2010).

The Diagnostic and Statistical Manual of Mental Disorders, 4<sup>th</sup> edition (DSM-IV) postpartum specifier strictly defined a Major Depressive Episode with onset of symptoms within four weeks after delivery (American Psychiatric Association, 1994). The Diagnostic and Statistical Manual of Mental Disorders, 5<sup>th</sup> edition (DSM-V) provides a "peripartum" specifier which is defined as the most recent episode occurring during pregnancy as well as in the four weeks following delivery (American Psychiatric Association, 2013). According to the International Classification of Diseases, 10<sup>th</sup> revision (ICD-10), postpartum onset is considered to be within six weeks after childbirth (Cox, 2004). However, in clinical practice and research, a common broader definition of the term "perinatal depression" is usually adopted, including onset of mood and anxiety symptoms that occur during pregnancy and through one year postpartum (Gaynes et al., 2005; Gavin et al., 2005). It is estimated that about one in two episodes of PD starts before childbirth (Wisner et al., 2013) and that depression in pregnancy is a risk factor for relapse after childbirth.

Concluding, timing of onset remains an area of controversy and further investigation is needed with respect to the biological and psychosocial factors underlying or mediating PD (Di Florio & Meltzer-Brody, 2015). In this thesis, PD is considered depression arising during pregnancy and throughout one year postpartum.

## Screening for PD

The gold standard for diagnosing PD is a clinical interview, with the Structured Clinical Interview for DSM-V (SCID-5) -a semi-structured interview guide for setting the major DSM-V diagnoses- to be the most well-known. A clinician or trained mental health professional, familiar with the DSM-V classification and diagnostic criteria, is usually the administrator (American Psychiatric Association, 2013).

Shorter, self-reported screening tools, such as the Edinburgh Postnatal Depression Scale (EPDS; Cox et al. 1987), the Patient Health Questionnaire-9 (PHQ-9; Spitzer et al., 1999), and the Beck Depression Inventory II (BDI-II; Beck, 2002) have been validated across several ethnic populations.

The most widely used method to screen for PD is the Edinburgh Postnatal Depression Scale (EPDS; Cox et al. 1987) which is also commonly used in research because it is reliable, well validated, and often more practical and cost-effective. It assesses emotional experiences over the past seven days using ten Likert-scale items. The psychometric properties of the EPDS in primary health care settings found to be: 86% sensitivity (individuals with the condition) 78% specificity (individuals without the condition) and 73% positive predictive value (individuals scoring positive in the test having a mental disorder diagnosed by clinical interview) (Cox et al., 1987).

The EPDS excludes somatic symptoms (i.e., changes in appetite, energy levels, and sleeping patterns) that are common among women in the perinatal period. Self-reported scales that include somatic items such as sleep difficulties and appetite disturbances may lead to high false-positive rates in pregnancy and postnatally, so scales excluding somatic questions are preferable for PD screening.

The UK National Screening Committee concluded that the EPDS is a "simple, safe, precise and validated screening test for which suitable cut-offs can be defined" (Hewitt et al., 2009; Hill, 2010). However, as the EPDS is not a diagnostic instrument, the Community Practitioners' and Health Visitors' Association (CPHVA) highlighted: "The EPDS should never be used in isolation, it should form part of a full and systematic mood assessment of the mother, supporting professional judgement and a clinical interview" (Henshaw et al., 2005). Although an optimal timing for PD screening during pregnancy and postpartum remains unspecified (Gaynes et al., 2005), following the healthcare and delivery patterns has been argued to provide adequate specificity and sensitivity. According to the American College of Obstetricians and Gynaecologists (ACOG), obstetric care providers should screen women at least one time during the perinatal period for depression and anxiety symptoms using a standardized and validated tool. A full evaluation of mood and emotional well-being (including screening for postpartum depression) during each patient's postpartum visit is recommended. Particularly, screening for postpartum depression at women's sixth week postpartum visit is recommended (ACOG, 2018). Also, screening at 34-36weeks of gestation has been found to be effective in predicting PD (Faisal-Cury & Menezes, 2012; Sutter-Dallay et al., 2012). During postpartum,

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screening as early as 24-48h postdelivery, before hospital discharge, is not uncommon (Austin et al., 2013), but might lead to false-positive screens as a result from unresolved "baby blues" or from the physical and emotional disturbances associated with a complex delivery or an unexpected outcome (Hannah et al., 1992). Finally, screening at six, eight and twelve weeks postpartum has been shown to be efficient in the identification of women at risk for PD (Wickberg & Hwang, 1997), however, this has not been confirmed by most recent studies.

## **Prevalence of PD**

Prevalence rates of PD range from 16% during pregnancy and nearly 20% for new mothers (WHO, 2017). It is estimated that 20% of women in industrialized countries meet the criteria for major or minor depression diagnosis sometime during pregnancy, with a similar or higher percentage to meet the diagnostic criteria in the first year postpartum (Gavin et al., 2005).

Major depression accounts for 20-50% of diagnosed depressive disorders during the perinatal period (Dietz et al., 2007; Reck et al., 2008) with symptoms of depression and anxiety to be highly correlated during pregnancy (Lancaster et al., 2010; Leigh & Milgrom, 2008).

## **Risk factors for PD**

A lifetime history of depression or a prior depressive episode is among the strongest predictors of PD (Dennis et al., 2012; Flynn et al., 2004; Leigh & Milgrom, 2008; Meltzer-Brody et al., 2013; Milgrom et al., 2008; Rich-Edwards et al., 2006; Schmied et al., 2013). Established risk factors for PD include antenatal anxiety (Leigh & Milgrom, 2008), poor partner relationship (Schmied et al., 2013), low social support (Dennis et al., 2012; Leigh & Milgrom, 2008; Schmied et al., 2013), stressful life events (e.g., divorce, serious illness, death in the family), daily difficulties (e.g., work hassles, time pressures, financial strain) (Dennis et al., 2012; Lancaster et al., 2010; Schmied et al., 2013), premenstrual syndrome or premenstrual dysphoric disorder (PMDD) (Buttner et al., 2013), history of childhood trauma (Meltzer-Brody et al., 2013) and low socioeconomic status (Dennis et al., 2012; Schmied et al., 2013).

#### Sociodemographic factors

Sociodemographic factors such as age, race, education, and type of medical insurance have been associated with the onset of PD (Fisher et al., 2016). Becoming an adolescent mother has been suggested as one of the main sociodemographic factors increasing the risk of PD (OR= 3.14) (Silverman et al., 2017). In addition, race and ethnicity have been suggested as risk factors for PD, as it was found less likely for ethnic minority patients to obtain care for depression and to receive appropriate treatment when they do access care (Yim et al., 2015).

Moreover, intimate partner violence (IPV) has been suggested as a predictor of PD. During pregnancy, between 3% and 9% of women experience IPV (Tjaden, 2000; Vest et al., 2002). Research involving low-income perinatal participants revealed that up to 85% of women experiencing IPV during pregnancy were also found to experience depressive symptomatology (assessed via the EPDS). Notably, these participants found to be at significantly greater risk for suicidal ideation (Alhusen et al., 2014; Alhusen et al., 2015; Lacey et al., 2015). A secondary data analysis of maternal violent death, from the Centre for Disease Control and Prevention's (CDC) National Violent Death Reporting System (NVDRS), revealed that 54.3 % of pregnancyassociated suicides involved intimate partner conflict attributable to the suicide (Palladino et al., 2011).

Other sociodemographic factors related to perinatal depression include tobacco use (OR= 3.25), single status (not married or not living with a partner; OR= 2.86), age of 40 years or older (OR= 1.41) and unintended pregnancy (OR= 1.41) (Langan & Goodbred, 2016; Raisanen et al., 2014).

# **Biological factors**

The hormonal fluctuations that occur during the perinatal period aiming to prepare the body for childbirth and breastfeeding are suggested to contribute to the occurrence and establishment of depressive symptoms (Brummelte & Galea, 2010; Brummelte & Galea, 2016; Gutierrez-Lobos et al., 2002; Kornstein, 2003). Steroid and peptide hormones (e.g., cortisol, oestrogens, progesterone and oxytocin) change dramatically during the reproductive years, especially during pregnancy the postpartum (Brett & Baxendale, 2001).

Research evidence supports the hypothesis that an "oestradiol-withdrawal state" following the weeks of delivery contributes to postpartum depression as oestradiol levels continue to increase during the third trimester but drop dramatically after delivery (Bloch et al., 2003; Hendrick et al., 1998). This is in line with Bloch's et al. (2000) finding that women with a previous history of postpartum depression demonstrated increased negative affect in response to ovarian steroid withdrawal compared to women without a previous history of postpartum depression, suggesting that women at higher risk for depression may be more susceptible to large fluctuations in steroid hormone levels (Bloch et al., 2000).

Moreover, the effect of the corticotropin-releasing hormone in the regulation of steroid hormones and depression has been investigated. Corticotropin-releasing hormone is mainly produced in the hypothalamus and during pregnancy it is also produced in placenta, uterus, and ovaries regulating the pituitary-hypothalamus-adrenal axis for production of steroid hormones (Tsigos et al., 2002). The significant drop of corticotropin-releasing hormone that follows delivery and expulsion of the placenta subsequently leads to a reduced production of steroid hormones (e.g., oestrogen) that may increase the likelihood of depression during the first three months postpartum (Kammerer et al., 2006). However, the origin of this mechanism has not been yet clarified (Skalkidou et al., 2012).

Furthermore, approximately 7% of new mothers experience alterations in the thyroid gland during and after childbirth compared to 3-4% of women in the general population (Basraon & Costantine, 2011). According to Pedersen et al. (2007), there is some evidence supporting the inverse association of free thyroxine levels and total serum thyroxine concentrations with symptoms of perinatal depression (Pedersen et al., 2007). A recent study indicated that a dysfunctional thyroid autoimmunity is correlated with an increased risk for self-reported first-onset depression in a subgroup of women (during the first four months of gestation) (Wesseloo et al., 2018).

Glucose metabolism disorders during pregnancy may serve as predisposing factors for postpartum depression as well (Huang et al., 2015). Researchers observed that women with higher blood glucose levels (mean of 120 mg/dl vs. 114 mg/dl) had an elevated risk for postpartum depression after performing the glucose challenge test with 50g of glucose (Huang et al., 2015).

#### **Obstetrical complications**

Additional risk factors for PD include pregnancy complications (Lancaster, 2010). The linkage between caesarean delivery and postpartum depression has been examined and mode of delivery is not suggested as a significant predictor for perinatal depression; however, individuals required a non-elective caesarean delivery while having a strong preference for vaginal delivery found to be at increased risk for PD in the early postpartum period (Adams et al., 2012; Goker et al., 2012; Houston et al., 2015).

Risky pregnancy (i.e., performing emergency caesarean section or hospitalization during pregnancy) is also associated with an increased risk of PD. An increased incidence of PD is correlated with perinatal complications such as meconium passage, umbilical cord prolapse, and obstetric haemorrhages (Gaillard et al., 2014; Leigh et al., 2008; Mathisen et al., 2013; Mayberry et al., 2007).

Preterm delivery has been associated with an overall risk for postnatal depression (Silverman et al., 2017). There is some evidence indicating that mothers of very low birth weight infants are at higher risk for PD with a prevalence of up to 40% compared with mothers of term infants (Vigod et al., 2010). This is in line with Helle's et al. (2015) finding that mothers of newborns weighting <1500gr are four to 18 times at higher risk for postpartum depression (Helle et al., 2015). Meanwhile, the risk of poor obstetrical outcomes, such as preterm birth and low birth weight found to be increased when depression is experienced during pregnancy (Diego et al., 2004; Fransson et al., 2011; Grote et al., 2010; Halbreich, 2005; Ibanez et al., 2012).

Depression during pregnancy can lead to adverse pregnancy outcomes through various ways. First, previous research suggested that decreased prenatal care, decreased practice of recommended health behaviours during pregnancy, and increased risk of smoking and substance use in the perinatal period contribute as risk factors (Flynn et al., 2004). Second, it has been proposed that stress or depression during pregnancy may affect birth outcomes via the dysregulation of the hypothalamic-pituitary-adrenocortical (HPA) axis, stimulating the release of stress hormones (i.e., cortisol, catecholamines). These changes might lead in placental hypofusion and restriction of oxygen and nutrients to the foetus, resulting in the restriction of foetal growth or triggering preterm birth (Borders et al., 2007; Talge et al., 2007; Federenko & Wadhwa, 2004). Finally, another hypothesis is that antenatal depression might compromise the function of the immune system (Herbert & Cohen, 1993) which could lead to a reproductive tract infection precipitating preterm birth (Federenko & Wadhwa, 2004).

It is important to notice that depression during pregnancy has been identified as a risk factor for preterm birth and low birth weight while preterm birth and low birth weight have been highlighted as risk factors for postpartum depression. Considering the previously established linkage between depression during pregnancy and postpartum depression (Lancaster et al., 2010), the crucial role of early screening, detection and monitoring of depressive symptomatology during pregnancy is emerging.

#### Effects of PD

#### Effects on the individual

During pregnancy, women with depression experience a variety of physical symptoms including complaints of gastrointestinal distress, headaches, dizziness, shortness of breath, and cardiac symptoms (Kelly et al., 2001). Further consequences of depression during pregnancy include the onset of medical complications (e.g., increased risk for preeclampsia), more severe forms of hyperemesis gravidarum, difficulties in performing usual activities and daily routines, prolonged sick leave, low attendance of prenatal care, poor diet, tobacco, alcohol, and other harmful substance abuse (McCue Horwitz et al., 2007; Qiu et al., 2009). Maternal depression is also associated with financial stress and lower socioeconomic status (McCue Horwitz et al., 2007).

PD -especially when linked to suicidal ideation or thoughts of self-harm- has been connected with long-term somatic and psychiatric morbidity (Iliadis et al., 2018). Self-harm ideation is more usual than attempts or deaths, with self-harm thoughts during pregnancy and postpartum to range from 5% to 14% (Lindahl et al., 2005). Suicides found to account for up to

20% of postpartum deaths (Lindahl et al., 2005) and remain a leading cause of maternal death in the UK (Cantwell & Oates, 2011).

#### *Effects on child and mother-child interactions*

Considerable evidence demonstrated that if the mother experiences depression or anxiety during pregnancy, the is an increased likelihood for the child to experience neurodevelopmental problems (Talge et al., 2007). Moreover, as previously mentioned, women with perinatal depression are at increased risk of maternal suicide. Foetal exposure to maternal suicide attempts during pregnancy has been linked to developmental disabilities and congenital abnormalities (Gentile, 2011; Gidai et al., 2010). In the postnatal period, mothers with depression may exhibit decreased maternal sensitivity and attachment with the infant while an increased risk of infanticide has been reported (Campbell et al., 2004; Lindahl et al., 2005; McLearn et al., 2006; Paulson et al., 2006). Mothers experiencing depression are also less likely to continue breast-feeding, which has been declared to precipitate a negative cycle because breast-feeding cessation could exacerbate women's anxiety and depression (Dias & Figueiredo, 2015; Figueiredo et al., 2014; Ystrom, 2012).

PD has also been associated with difficulties in parenting, particularly the early motherinfant interaction that are, in turn, associated with different problems among children (Milgrom et al., 2004). These coincidental difficulties can be divided in three groups (Murray et al., 2010): withdrawn interactions, hostile and intrusive interactions, and general sadness and insensitivity. These are subsequently associated with an increased risk of worse child emotional, behavioural, and cognitive outcomes. For example, according to Murray's et al. (2011) study, when a mother's vocal interactions signal sadness and attachment needs are not fulfilled, there is more than a fourfold increased risk for the child to develop emotional problems in adolescence (Murray et al., 2011).

#### Maternal and paternal perinatal depression

The transition to fatherhood can be challenging, raising increased psychosocial demands for fathers. Paternal active involvement and wellbeing contribute as major influences for the child's wellbeing (Genesconi & Tallandini 2009; Kowlessar et al. 2015).

Despite the high prevalence rates of paternal PD (i.e., a Major Depressive Episode occurring in new or expectant fathers during the perinatal period) and the paramount role of paternal mental health to family functioning, perinatal mental health services remain women-centred, and evidence is still limited with respect to the availability of prevention guidelines and treatment options for paternal PD.

Paulson and Bazemore's (2010) meta-analysis revealed a pooled mean prevalence of 10.4% for paternal PD, which is twice the rate found in the general male population (Anokye et al., 2018). According to a recent meta-analysis, the meta-estimate for paternal PD was 8.4% (95% confidence interval [CI], 7.2%–9.6%) (Cameron et al., 2016).

The existence of gender-related differences in the symptoms of perinatal depression has been claimed, suggesting "male specific" symptoms in paternal PD (e.g., acting out, aggressiveness, low impulse control, anger attacks, irritability, low stress threshold, restlessness, risky or socially unacceptable behaviour, and substance abuse) and behavioural patterns (e.g., withdrawal from relationships, overinvolvement with work, denial of pain, rigid demands for autonomy (Madsen & Juhl, 2007; Winkler et al., 2006).

Untreated paternal PD could lead to developmental problems and mood or anxiety disorders in the child (Edward et al., 2015). Longitudinal data suggested that paternal PD may be

associated with emotional and behavioural problems in early childhood (Ramchandani et al., 2008), lower social and psychological well-being (Hancock et al., 2013) and internalized behaviour problems in children of three to twelve years of age (Pihlakoski et al., 2013).

The direction of the relationship between paternal PD and maternal PD has not yet been clarified. Maternal PD has been identified as one of the strongest predictors of paternal PD estimating that 24%-50% of men whose partners are depressed also meet the criteria for minor or major depression (Areias et al., 1996; Goodman, 2004). Furthermore, paternal PD was found to increase the risk for continued or worsened maternal PD symptoms at six months postpartum (Paulson & Bazemore, 2016).

The risk for the offspring to develop mood or anxiety disorders was found to be significantly higher when both parents were depressed and did not differ according to whether the affected parent was the mother or the father (Havinga et al., 2017).

Overall, it is evident that untreated perinatal depression is associated with serious shortterm and long-term adverse effects for the mother, the father, the child and the family (Flynn et al., 2004; Marcus et al., 2011; O'Hara & Swain, 1996; Stowe et al., 2005; Wisner et al., 2002). Although the main focus of this thesis is maternal PD, there is an obvious gap in family-focused and partner-focused (partner refers to someone with whom the individual shares an intimate relationship), evidence-based interventions exploring prevention and treatment of perinatal depression.

#### **Treatment options for PD**

For pregnant and postpartum women with mild to moderate depression, the recommended first-line treatment option is psychological or behavioural treatment without medication (Yonkers et al., 2009; Yonkers et al., 2011). For more severe depressive symptoms,

pharmacotherapy is suggested as an appropriate and effective treatment (Einarson, 2010; Yonkers et al., 2009).

Although guidelines for the detection and treatment of perinatal mental disorders, including PD, are available (National Institute for Health and Care Excellence [NICE], 2014), most perinatal medication guidelines and recommendations are not specifically developed for pregnant women. As highlighted in a recent review by Molenaar, guidelines include limited information on the "measures of implementation and audit of the proposed measures" and none of them provides treatment options for patients with current depressive symptomatology despite treated with antidepressants (Molenaar, 2018). In addition, according to Santos et al. (2017), guidelines lack implications on emerging clinical questions and on updated evidence (Santos et al., 2017).

#### Psychosocial and psychological interventions

Psychosocial and psychological interventions (e.g., nondirective counselling, professional and lay home visits, telephone-based peer support, cognitive behavioural therapy, and interpersonal psychotherapy) are proven efficacious treatment options for PD (Cuijpers et al., 2008; Dennis & Hodnett, 2007; Sockol et al., 2011).

The most widely studied interventions have been cognitive-behavioural therapy (CBT) and interpersonal therapy (IPT). Briefly, CBT focuses on problematic patterns of thoughts and behaviours that may be associated with depression (e.g., change maladaptive patterns of thinking, increase activities that improve mood, solve life problems), while IPT targets an individual's social functioning domains (e.g., role transitions, grief, interpersonal deficits).

As found in Cuijpers et al. (2008) meta-analysis, psychological treatments led to moderate improvements compared to controls (effect size= .61), a finding similar to the results

demonstrated in the general depression treatment literature (Cuijpers et al., 2008). Interestingly, trials comparing psychosocial interventions to wait-list controls reported higher effect sizes than those comparing psychosocial interventions to treatment-as-usual (effect size= .96 vs. .41). In addition, small differences between psychotherapy modalities were found, suggesting that further assessment of potential moderators of the efficacy of those interventions in perinatal populations is needed (Cuijpers et al., 2008).

A recent meta-analysis, examining the efficacy of CBT interventions in perinatal populations, revealed significant decreases in depressive symptoms in the intervention groups compared to controls, with effect sizes range from small to medium (Sockol, 2015). Results indicated that prevention studies were more effective when initiated later in pregnancy or during postpartum. According to the author "it may be most effective to help women address potential concerns after their infants are born, as women may find the information more immediately relevant and helpful" (Sockol, 2015). However, barriers including stigma and poor healthcare experiences (Hadfield & Wittkowski 2017; Megnin-Viggars et al. 2015) or lack of childcare, distance or difficulty to travel (Goodman, 2009; O'Mahen & Flynn 2008), might hinder women's access and compliance to treatment.

Concluding, the lack of long-term follow-up as well as the usage of self-reported measures' cut-off scores as entry criterion in some treatment trials have been highlighted as limitations, adding substantial uncertainty to the aforementioned findings (Cuijpers et al., 2008; O'Hara & McCabe, 2013, Sockol et al., 2011).

#### Antidepressants

Perinatal antidepressant use has been debated for the past decades. The prescription rate of selective serotonin reuptake inhibitors (SSRIs) during pregnancy ranges from 3.7% in the UK

(Charlton et al., 2015) to 6.2% in the USA (Andrade et al., 2008). Potential associations of antidepressant use during pregnancy with adverse child outcomes have been reported (Simoncelli et al., 2010). Specifically, research demonstrated increased risks for cardiovascular malformations (especially with paroxetine) (Grigoriadis et al., 2013), persistent pulmonary hypertension of the neonate (PPHN) (Kieler et al., 2012), preterm delivery and lower birth weight (Ross et al., 2013), and psychiatric disorders in the offspring (e.g., mood disorders, autism spectrum disorder and behavioural disorders including attention deficit hyperactivity disorder) (Liu et al., 2017). However, such findings have not been confirmed by a significant proportion of studies (Furu et al., 2015; Huybrechts et al., 2015; Hviid et al., 2013; Man et al., 2018).

On the other hand, untreated mental illness during pregnancy is not free of risk for the child either. Untreated maternal depression has been associated with premature delivery and low birth weight (Grigoriadis et al., 2013; Grote et al., 2010; Jarde et al., 2016). In the long-term, maternal mental illness during pregnancy may increase the risk for behavioural, emotional, cognitive and motor problems during childhood (Field, 2011; Goodman et al., 2011; O'Connor et al., 2003; Talge et al., 2007) and psychiatric disorders during adolescence (Pearson et al., 2013, Van den Bergh et al., 2008).

Much progress has been made in addressing the benefits and limitations of perinatal antidepressant use, however, previous evidence is mostly originated from retrospective observational studies with a lack to differentiate the effects of antidepressants from other shared risk factors. Details with respect to significant confounders, such as co-morbidity, co-medication, smoking behaviour, and socio-economic status are missing.

#### Treatment compliance

Treatment compliance among perinatal individuals experiencing PD is often perplexed by their treatment preferences and by social stigma. Pregnant and postpartum women suffering from depression may experience significant stigma attributed to having a mental illness during the time period supposed to be viewed as a "happy time of life." The stigma of perinatal depression has been related to notions of being a "bad mother" (Bilszta et al., 2007; Buultjens & Liamputtong, 2007; O'Mahen et al., 2012).

Literature consistently indicates postpartum women's preference for psychotherapy over antidepressant medication when available (Boath & Henshaw, 2001; Ride & Lancsar, 2016; Whitton et al., 1996). Perinatal individuals experience persistent anxiety with respect to the potential harmful effects of antidepressants on the infant, either in utero or via breast milk (Turner et al., 2008). Misri et al. (2010), followed 50 women with depression (recruited in pregnancy to one month postpartum), thirty of whom complied with medication and twenty who did not. Differences between the two groups were examined and results revealed that adherers were more accepting of their depressive disorder compared to the non-compliers who demonstrated less insight, reported fear of foetal exposure and perceived that their symptoms did not require the medication. Another study showed that women were reluctant to initiate medication, even after education, reporting fear of addiction and beliefs that the symptoms would resolve without medication (Dennis & Chung-Lee, 2006). Similarly, Boath's et al. (2004) study demonstrated particularly low adherence to medication in breastfeeding mothers while non-compliance to treatment was common (Boath et al., 2004).

Finally, factors such as availability, accessibility, and affordability are all crucial for new mothers who may face practical difficulties such as bringing a child to an appointment or

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arranging childcare, dealing with potential changes in family income, and having or not the opportunity to choose their preferred type of therapy (Goodman 2004; O'Mahen et al., 2012). Concluding, the conceptualization of clear, concise and updated, evidence-based information with respect to established treatment options is crucial. Above all, the need to explore the effectiveness of alternatives to traditional psychological and pharmacological treatments for PD, taking into consideration perinatal women's preferences for nonpharmaceutical treatment options, is emerging.

# PHYSICAL ACTIVITY (PA), EXERCISE AND PERINATAL DEPRESSION Definitions

PA is defined as any bodily movement produced by skeletal muscles that results in energy expenditure beyond resting expenditure. Exercise is a "subset of PA that is planned, structured, repetitive, and purposeful in the sense that improvement or maintenance of physical fitness is the objective" (Thompson et al., 2016).

Although energy expenditure is increased during PA, it does not always reflect exercise and should not be confused with fitness. Thus, PA can be categorized either in different contexts, such as leisure time, exercise, sports, occupational, household, and transportation activities, or by intensity, i.e., low, moderate, and vigorous (American College of Sports Medicine [ASCM], 2017).

#### Suggested mechanisms

#### The endorphin hypothesis

The endorphin hypothesis is one of the proposed mechanisms through which exercise may improve psychological health and enhance wellbeing. The endorphin hypothesis suggests that opioids and endocannabinoids released during exercise, stimulate a sense of euphoria with subsequent beneficial mental health outcomes (Dietrich & McDaniel, 2004). However, it is debated whether plasma endorphins represent endorphins' activity in the brain. Previous studies have reported increased plasma endorphins after acute and chronic exercising (Bortz et al., 1981; Carr et al., 1981; Farrell et al., 1982), but there is an absence of recent studies clarifying a potential direct link of the elevated endorphinic activity and the reduction of depressive symptoms in perinatal women.

#### The Exercise-Glucocorticoid Paradox

It is well established that acute exercise is a potent modulator of the release of hypothalamic pituitary adrenal axis (HPA) hormones (Elenkov & Chroussos, 2000; Kjaer & Dela, 1996; Mastorakos et al., 2005). Exercise activates the HPA axis and increases the levels of cortisol. Cortisol is a glucocorticoid steroid hormone, regulated and released through the HPA axis. Acute exercise increases the levels of cortisol, while chronic exercise may also increase basal cortisol levels (Kanaley & Hartman, 2002; Stranahan et al., 2008).

The cortisol serves as a mediator between chronic stress and depression. Chronic stress has been argued to trigger and induce depression (Beck & Bredemeier, 2016; Hammen, 2005; Holsboer & Ising, 2010; Ingram & Luxton, 2005; Lupien et al., 2009, Ulrich-Lai & Herman, 2009). Increased cortisol levels, as a response to both exercise and chronic stress/depression, can lead to beneficial and detrimental effects accordingly. A few authors identified the existence of an "Exercise-Glucocorticoid Paradox" (Adlard & Cotman, 2004; Chen et al., 2016; Schoenfeld & Gould, 2012). This paradox refers to the contradictory but, in both cases, mediated by elevated cortisol levels effects of exercise and chronic stress in cognition, mood, stress coping, and neuroplasticity. Chen et al. (2016) suggested three potential explanations to this paradox.

According to the first hypothesis, while chronic exercise decreases, chronic stress increases novel stress-responsive cortisol. Second, while chronic exercise increases, chronic stress reduces dopamine in the median prefrontal cortex. The third hypothesis supports that a potential explanation of the paradox could be that chronic exercise does not induce changes or upregulates, while chronic stress diminishes the expression of the mineralocorticoid receptor (for a review see Chen et al., 2016).

During pregnancy and postpartum, the levels of cortisol, adrenocorticotropic hormone (ACTH), corticotropin-releasing hormone (CRH) and corticosterone binding globulin (CBG) fluctuate significantly. The growth and development of the placenta that produces its own steroid hormones and proteins which can interfere with the mother's hormonal equilibrium and homeostasis, has been supported to be partially responsible for the changes in the stress circuit (Glynn & Sandman, 2012). Typically, cortisol levels gradually increase in pregnancy, reaching a peak at delivery and then abruptly decline within the first days postpartum (Thompson, 2008). In order to respond to the elevated levels of cortisol during pregnancy, reduced activation of CRH neurons help pregnant women to become less responsive to external stressors (Kammerrer et al., 2002). When there is a dysregulation in the HPA axis, the reduction of CRH fails to occur and high levels of cortisol may lead to hypercortisolemia during pregnancy (Pariante, 2006), which subsequently increases a woman's risk of developing depressive symptoms (Penninx et al., 2013). However, the particular mechanisms underlying the mild hyporesponsivity in the HPA axis during the perinatal period are not fully understood and further research is needed.

Concluding, although the antidepressant effects of exercise are well-established, the underlying mechanisms of these effects remain under debate and to the author's best knowledge, are not tested in perinatal individuals experiencing depressive symptoms.

# **Psychological processes**

Psychological processes, through which exercise may influence depression, include improvements in self-efficacy for exercise and daily life coping, the development of social support networks, and the achievement or maintenance of body image satisfaction.

Exercise self-efficacy is defined as "one's belief about the capability to successfully engage in incremental bouts of physical activity" (Blacklock et al., 2007). According to the selfefficacy theory, individuals' depressive symptoms may become less severe as their self-efficacy increases (Bandura, 1977; Bandura 1997). Self-efficacy has been supported as an independent mechanism for the antidepressant effects of exercise in adult samples (Annesi, 2012; Craft, 2005; Ryan, 2008).

Moreover, it is widely accepted that building social support networks through exercise has a variety of positive effects on mood and depression among adult individuals (Makino et al., 2015; McAuley et al., 2000). Social support can be conceptualized as the helpful resource individuals perceive available to them incorporating both formal and informal relationships (Gottlieb & Bergen, 2010). There is a growing body of research investigating mediators of the path from social support to exercise in order to describe the potential psychological mechanisms through which social support enhances exercise participation (Anderson et al., 2007; Duncan & McAuley, 1993; McAuley et al., 2003; Molloy et al., 2010). One of these mechanisms suggests that "receiving social support may help a person with regard to his/her self-regulative attempts by enabling one's abilities to master challenges'' (Benight & Bandura, 2004; Schwarzer & Knoll, 2007). Specifically, social support enhances self-efficacy and self-monitoring because individuals tend to evaluate more often and more precisely whether they performed in accordance with their intended goals (Lippke & Ziegelmann, 2008). Also, action planning for

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exercise -the plan design to modify a certain behaviour or adopt a new behaviour- as a selfregulative strategy, can be reinforced by both perceived and received social support (Molloy et al., 2010).

Sudden body changes that differ from pre-pregnancy may trigger perinatal women's body image dissatisfaction (Skouteris et al., 2005). Dissatisfaction with changing body image can contribute to some women having anxiety, stress and mood disturbances (National Institute for Health and Care Excellence [NICE], 2009). It is well established that body satisfaction during pregnancy and postpartum is inversely related to perinatal depression (Clark et al. 2009; Downs et al. 2008; Duncombe et al. 2008; Rauff & Downs 2011; Roomruangwong et al., 2017; Sweeney & Fingerhut 2013). Body image dissatisfaction has been found to remain comparatively stable during pregnancy (Clark et al., 2009; Rocco et al., 2005; Skouteris et al., 2005) and tends to increase during postpartum (Clark et al., 2009; Rallis et al., 2007).

Finally, the possibility of exercise to provide distraction or "time out" from rumination has been proposed as a mechanism for its antidepressant effect, however, this has received limited empirical support (Bahrke & Morgan, 1978).

# Maternal and neonatal benefits

Physical activity and physical exercise are related with numerous maternal and neonatal health benefits. Specifically, higher levels of pre-gestation or early gestation PA have been linked to a significantly lower risk of developing gestational diabetes (Tobias et al., 2011). Perales et al. (2020) argued that exercise during pregnancy can lead to a significantly reduced risk of excessive gestational weight gain and of both gestational diabetes and hypertension. Importantly, benefits of gestational exercise found to be maximized for individuals that were previously inactive. Increasing levels of PA before and during early pregnancy has been associated with a lower risk of preeclampsia (Aune, 2014). Moreover, there is supporting evidence of the beneficial effect of gestational exercise on cardiorespiratory fitness and the prevention of urinary incontinence (Perales, 2016). Meta-analytic evidence (Davenport et al., 2018; Shiri et al., 2018) concluded that pregestational exercise has a large effect on decreasing the severity of low back pain, pelvic girdle and lumbopelvic pain that can significantly impair maternal quality of life. Poyatos-Leon's et al. (2015) meta-analysis reported reduced nonelective caesarean delivery rates, when exercise was performed during the second and third trimesters and these findings have been confirmed by another meta-analysis (Di Mascio et al., 2016) including 2059 individuals with singleton, uncomplicated gestations. Further neonatal benefits of maternal exercise include reduced stress response and healthier birth weight (Mudd et al., 2013) as well as higher Apgar scores (Murtezani et al., 2014). Three meta-analyses reported minimal or no differences in infant birth weight between women who exercised during pregnancy compared to controls (Krammer & McDonald, 2006; Leet & Flick, 2003; Lockey et al., 1991). Finally, regular aerobic exercise during the lactation period appeared to improve maternal cardiovascular fitness without influencing milk production, composition, or infant growth (Gary & Quinn, 2001; Lovelady, 2011).

## **Current guidelines and future suggestions**

According to the American College of Obstetricians and Gynaecologists (ACOG), PA for mother and foetus is safe in most cases during the perinatal period (including lactating period) (Birsner & Gyamfi-Bannerman, 2020). Current international guidelines on PA for pregnant and postpartum women suggest that in the absence of contraindications they should i) undertake regular PA throughout pregnancy and postpartum, ii) do at least 150min of moderate-intensity aerobic PA throughout the week for substantial health benefits, iii) incorporate a variety of aerobic and muscle-strengthening activities while gentle stretching may also be beneficial.

Women who, before pregnancy, habitually engaged in vigorous-intensity aerobic activity, or who were physically active, are advised to continue these activities during pregnancy and the postpartum period. Postpartum individuals are advised to resume PA routines as soon as medically safe, based on the delivery mode and the incidence of medical or surgical complications (WHO, 2020). Whereas less information is available regarding exercise guidelines during the postnatal period, the different phases of the postpartum should be taken into consideration before exercise prescribing. These phases include the acute postpartum period (i.e., first 6-12h postdelivery), the immediate postpartum period (i.e., hospital discharge to 6weeks postpartum, depending on delivery type), and the later postpartum period (i.e., 6weeks to 1year, depending on breastfeeding routines).

In general, perinatal women are advised to avoid activities in supine position after the first trimester of pregnancy and discouraged to participate in contact activities with high risk of abdominal trauma or imbalance and scuba diving (Birsner & Gyamfi-Bannerman, 2020). Specific considerations and safety issues with respect to PA and exercise during pregnancy include ensuring adequate caloric intake before engaging in physical exercise and hydrating before, during, and after exercise, avoiding activities that require jumping movements and quick changes in direction, minimizing prolonged isometric contraction and motionless standing, avoiding exercise in a hot humid environment, and ensuring comfortable and proper exercise footwear and clothing. (ACOG, 2015). Women are also advised to wear supportive bras during exercise and adopt exercise to breastfeeding routines while constant attention should be given in the type of birth and its impacts on musculoskeletal health (ACOG, 2015).

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Although the body of knowledge on perinatal PA and exercise is increasing, studies are heterogeneous with respect to PA type, intensity, duration, and assessment tools. Recently, the WHO stated that there is insufficient evidence to determine if the associations between PA and health outcomes vary by type or domain or timing (i.e., pre-pregnancy, antenatal or postnatal) of physical activity (WHO, 2020).

Thus, the question is not "if" but "how" people should exercise during the perinatal period. In this respect, i) further research is needed to understand in more detail the dose-response and the domain-specific relationship of PA with mental health outcomes in perinatal populations ii) PA and exercise plan development, apart from the physiologic, biochemical and musculoskeletal assessment, should consider perinatal individuals' psychological changes, challenges and needs, as well as their cultural background.

Based on the above, the aim of the first study of this thesis was to conduct a systematic review and meta-analysis in order to synthesize evidence from RCTs investigating the effect of PA and exercise-based interventions on PD symptoms among perinatal individuals recruited via obstetric care practices. The aim of the second study was to implement a two-arm RCT in order to evaluate the effectiveness of an Exercise Counselling (EC) intervention (from 27weeks gestation to 10weeks post-birth, based on the Transtheoretical Model (TTM) of change, compared to Perinatal Wellbeing Education (PWE), on reducing the depressive symptoms of perinatal individuals recruited via obstetric care practices. Finally, the aim of the third study was to conduct a qualitative study with semi-structured interviews to explore participants' views and experiences deriving from the Exercise Counselling (EC) intervention and evaluate the intervention's acceptability.

## **CHAPTER III**

# **RESEARCH PAPER 1**

# EXERCISE FOR PERINATAL DEPRESSIVE SYMPTOMS: A SYSTEMATIC REVIEW AND META-ANALYSIS OF RANDOMIZED CONTROLLED TRIALS IN PERINATAL HEALTH SERVICES.

#### Abstract

Exercise improves PD symptoms, but reports call for more robust evidence. This systematic review and meta-analysis aimed at synthesizing evidence exclusively from randomized controlled trials (RCTs) examining the effects of exercise on PD symptoms in women recruited via perinatal health services. Nine e-databases and fifteen systematic reviews were searched for relevant RCTs. Exercise-specific tools extracted/coded data. A meta-analysis using a random effects model (Standardized Mean Difference [SMD]) investigated the effects of exercise on PD scores post-intervention. From 285 records, 14 RCTs (1.601 participants) were considered eligible including two RCTs with clinically diagnosed PD women. Exercise showed a statistically significant small overall antidepressant effect (SMD = -.21, 95% CI = -.31, -.11, p= .0001) with low/non-significant heterogeneity (Q = 17.82,  $I^2 = 16\%$ , p= .27). Only the fail- safe criterion recorded marginally significant publication bias, but trim-fill analysis added no study. Sensitivity analyses increased the overall effect in RCTs showing lower risk of bias or delivering ≥150min/week moderate intensity aerobic exercise. Subgroup analyses revealed significant antidepressant effects for exercise across various settings, delivery formats, depressive symptoms severities and outcome measures used. Heterogeneity was low/nonsignificant in all analyses ( $I^2 \le 50\%$ ). Hedges' g corrections did not influence the results.

Study limitations include the small number of available trials and clinically diagnosed samples with PD and the variety of exercise modalities. Exercise improved PD symptoms, especially in RCTs with lower risk of bias or with  $\geq$ 150min/day moderate intensity aerobic exercise interventions. Findings are clinically useful but more RCTs for clinically diagnosed women with PD are needed for firmer conclusions.

# Introduction

Depression is characterized mainly by anhedonia and psychosocial impairment and represents a common disorder (American Psychiatric Association, 2013). Perinatal depression (PD) may occur at any time during pregnancy or within 12 months after delivery (American College of Obstetricians and Gynaecologists [ACOG], 2020). The risk for PD is high in the 2<sup>nd</sup>-3<sup>rd</sup> trimesters of gestation (Bennett et al., 2004) and 2-3 months postpartum (O'Hara & Wisner, 2014; Stuart-Parrigon & Stuart, 2014). This mental health illness affects 15.6% of pregnant and 19.8% of postpartum women (World Health Organisation [WHO], 2017), and it is related with marital issues, conflictual couple relationships and partner depression (Goodman et al., 2011; Tronick & Reck, 2009). Also, PD is associated with impaired infant development, with mother-infant relationship and with infant-harm or self-harm behaviors (Pope et al., 2013; Wisner et al., 2013). In addition, PD is linked to sedentariness, which may trigger worse mood, depression/somatic symptoms that can interfere with social/daily activities (Poudevigne & O'Connor, 2006).

Noteworthy, PD remains widely untreated (Jarde et al., 2016). When psychological or drug therapies are prescribed, inaccessibility, childcare, costs or stigma emerge as key barriers (Dennis & Chung-Lee, 2006). Antidepressants are often rejected (Kothari et al., 2019; Turner et al., 2008) and, when prescribed, may cause delays in early developmental milestones and behavioral disturbances during infancy (Mortensen et al., 2003; Pedersen et al., 2010). Thus, PD treatments may show up to 40% attrition (Klier et al., 2001; O'Hara et al., 2000). Additional or alternative interventions are thus essential. Exercise could play an important treatment role, especially since it is widely preferred by mental health patients (Sigurdsson et al., 2008).

Exercise is typically safe for perinatal women (ACOG, 2020) and linked to lower PD symptoms in various meta-analyses (Standardized Mean Differences [SMDs] range: -.22 to -.81). However, several issues in these studies warrant careful consideration. Particularly, previous studies recorded wide confidence interval and high/significant heterogeneity (Daley et al., 2015a; Daley et al., 2009; Nakamura et al., 2019). Also, they allocated trials with both mindful activities (e.g., yoga) and exercise interventions (Carter et al., 2019; Davenport et al., 2018). However, mindful activities have a different structural concept to exercise; mindful activities are performed with a profound inwardly directed contemplative focus, whereas in exercise there is a relative disconnect between mind and kinesthesis (La Forge, 2005). Previous studies also reported including (a) randomized controlled trials (RCTs) and observational studies (Nakamura et al., 2019) (b) RCTs and quasi-RCTs (McCurdy et al., 2017; Poyatos-León et al., 2017) or (c) low, low-medium or medium quality trials (Carter et al., 2019; Davenport et al., 2018; Poyatos-León et al., 2017; Pritchett et al., 2017). Further, follow up measures were not reviewed, bringing into question the enduring effects of exercise. Finally, risk of bias was analyzed with tools not structured for physical therapy interventions (e.g., exercise), thus critical exercise aspects such as attrition were overlooked. However, attrition mirrors treatment acceptance and warrants inclusion in risk of bias analysis, especially since exercise shows increased time/effort demands (Turk et al., 1984) and depression lack of energy/interest (American Psychiatric Association, 2013).

Also, previous meta-analyses have often reviewed trials comparing exercise interventions vs. control groups assigned to usual care involving exercise conditions; e.g., controls receiving general recommendations to exercise (Vargas-Terrones et al., 2019) or controls on waiting list to exercise (Haruna et al., 2013). However, such comparisons may mask the true effects of exercise

interventions because exercise conditions in controls may contribute to depressive symptom relief (Schuch et al., 2017). Hence, examination of comparisons of exercise interventions with controls that do not involve exercise conditions appears to be essential.

In addition, previous meta-analyses reported that they could not record the optimum type/dose of exercise for PD (Daley et al., 2015a; McCurdy et al., 2017; Nakamura et al., 2019). Moreover, the recent review of the American College of Sports Medicine (ACSM) and the Recommendation Statement of the US Preventive Services Task Force (USPSTF) did not conclude on the causal relationship of exercise with improved PD or on the optimum type/dose of exercise (Dipietro et al., 2019; O'Connor et al., 2019; USPSTF, 2019). Also, the ACOG Committee Opinion (2020) reports that exercise can be an essential factor in the prevention of postpartum depression, and recommends 20-30min/day of moderate intensity exercises for most if not all days of the week. However, the ACOG Committee Opinion (2020) also calls for investigation of the optimum exercise type/dose. Relevant investigation should thus be prioritized, taking into account that the WHO (2020) guidelines for lower risk of postpartum depression recommend aerobic type exercise at a dose of moderate intensity for  $\geq 150$ min/week.

Another issue in the literature is the lack of evidence for the PD-reducing effects of exercise in perinatal health settings. Particularly, all previous meta-analyses have included a number of exercise trials implemented in various community settings (Carter et al., 2019; Davenport et al., 2018; Nakamura et al., 2019). In light of this evidence, this study focused on RCTs with participants sampled from exercise interventions provided through perinatal health services to examine if such exercise programmes can be accepted (low attrition) and effective in reducing PD symptoms in routine practice settings. Relevant findings could support future implementation of exercise trials or interventions in those specific settings.

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Considering the issues that were identified above, the aim of this systematic review and meta-analysis was to synthesize evidence from RCTs examining the effects of exercise interventions on PD symptoms, among perinatal women recruited and exercised through perinatal health services. Part of the analyses evaluated risk of bias with an exercise specific tool, excluded comparisons to controls involving exercise conditions and investigated the antidepressant effects of aerobic type exercise interventions at a dose of moderate intensity for  $\geq$  150min/week.

## Method

The Bioethics Committee of the first author's Institution (University of Thessaly) has provided relevant permission for the protocol and implementation of this study (UTH-2-3/05-October-2018). This research synthesis was prepared in accordance to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines that ensures quality via a 27-item standard checklist (Moher et al., 2009). The PRISMA checklist for the current study can be found in Supplemental Table S 1.

#### Literature search and study selection

A literature search via nine e-databases was independently performed by the second and fourth author for English speaking articles from January 1, 1990 to July 30, 2019 and was updated in February 2020. Details concerning e-databases, keywords, MEdical Subject Heading (MESH) terms and search strategy for PubMed and Scopus are presented in Supplemental Table S 2. Hand-searching for additional RCTs included screening of reference lists of 15 systematic reviews (see Supplemental Table S 2).

# Eligibility criteria

Trials were eligible on the basis of the following characteristics: (1) pregnant or postpartum women recruited via perinatal health services excluding women with psychiatric diagnoses other than depression; (2) exercise interventions (excluding mindful activities) as defined by the American College of Sports Medicine (Pollock et al., 1998); (3) comparisons of exercise interventions to defined control conditions; (4) outcome measures of depressive symptomatology; and (5) studies with a design of an RCT with depression symptomatology as a primary or secondary outcome measure.

#### Data collection and extraction

The second and fourth author independently reviewed title/abstract assessments. Data were checked for accuracy and duplicates and full text articles were allocated. Consensus on the eligible trials was reached. If no agreement could be reached, it was planned the third author would decide. Data from full text articles were independently extracted via standard (prepared) exercise-specific forms by the second and fourth author based on the Participants, Interventions, Comparisons, Outcome measures, and Study design (PICOS) criteria (Moher et al., 2009). Authors of eligible trials were contacted by e-mail when clarifications for the studies were essential.

#### Coding of eligible trials

Eligible trials were coded via the PICOS criteria: i) participants: depressive symptom severity, physical activity levels and concurrent mental health therapies at baseline, ii) interventions: intensity, type, session length/frequency, weekly duration, total duration in weeks, attendance rates and average dropout rates from intervention, iii) comparisons to perinatal care control conditions: usual care, antidepressants, counseling, wait-list, or other defined conditions, iv) outcomes: self- or clinician-reported outcomes, v) study design: RCTs with lower ( $\geq 6$ ) or higher (< 6) risk of bias scores on the Physiotherapy Evidence Database (PEDro) scale (de Morton, 2009).

# Risk of bias assessment

Eligible trials were evaluated for risk of bias with the PEDro scale (de Morton, 2009). This scale is designed for physical therapy interventions such as exercise and represents a valid measure of the methodological quality of clinical trials (Maher et al., 2003). Also, it is increasingly used in various research areas (Gorin et al., 2012; Machado et al., 2015) and in the area of exercise for anxiety or major depression (Ensari et al., 2015; Morres et al., 2019a). However, is has not been used in the area of exercise for PD symptoms. The PEDro scale evaluates interval validity via 10 items and the overall scoring ranges from 0 to a maximum score of 10, with higher scores indicating better design quality (Maher et al., 2003). Items evaluate: random allocation; concealed allocation; between-group comparisons; point estimates and variability measures; blinding patients; blinding therapists; blinding assessors; baseline balance; intention-to-treat; lower than 15% dropouts. Due to inability to blind participants and therapists, our trials received a score of 0 on the relevant items. To this extent, 8 points was the maximum PEDro score in our study. The PEDro scale reports a benchmark score of  $\geq 6$  for classifying lower risk of bias trials. The second and fourth author independently evaluated the design quality of each trial, and sought consensus on their evaluations. In case of discrepancies in data evaluation, it was planned the third author would decide. Cohen's Kappa algorithms were computed, and interpreted via the Landis and Koch (1977) reference to assessing the interrater agreement.

Statistical analysis

The software Review Manager (RevMan) Version 5.3 (Review Manager, Nordic Cochrane Centre, 2014) was used for statistical pooling. The primary outcome measure was standardized mean difference (SMD) in post-intervention scores of depression between interventions and controls. Based on Cohen's d standards (Cohen, 1992), SMDs of .20, .50 and .80 are considered small, moderate or large, respectively. A random effects model was selected to reduce the bias stemming from the potential heterogeneity between trials. Statistical heterogeneity was assessed with the Cochran's Q and I<sup>2</sup> statistics taking into account that I <sup>2</sup> values up to 40% are unlikely to be important (Higgins & Green, 2011).

Publication bias for the main composite analysis was assessed with visual inspection of the funnel plots, and with computation of the Begg–Mazumbar Kendall's tau (Begg & Mazumdar, 1994), the Egger bias test (Egger et al., 1997) and the fail-safe criterion (5k + 10) (Rosenthal, 1979). In case of publication bias, the trim-fill statistic was computed on the right and left side of the plot (Duval & Tweedie, 2000). This test technically removes or adds trials to balance an asymmetrical funnel plot and adjusts the effect size to provide an unbiased estimate of the effect. Level of significance was set at .05.

# Sensitivity analyses

Three sensitivity analyses examined inflation of the overall exercise effect. First, we coded trials with lower risk of bias (PEDro score  $\geq 6$ ) given the relationship of higher risk of bias with overestimation of treatment efficacy (Moher et al., 1998; Schulz, 2001; Schulz et al., 1995). Second, we coded trials with non-exercise controls because exercise conditions incorporated in controls may decrease depression scores and mask the true interventions effects (Schuch et al., 2017). A third sensitivity analysis coded trials with a dose of  $\geq$  150min/week moderate intensity aerobic exercise on account of a 3-fold consideration. Specifically, while the WHO (2020)

recommends this aerobic dose to pregnant women for lower risk of postpartum depression and the ACOG (2020) reports that aerobic exercise can be an essential factor in the prevention of postpartum depression, the ACSM, USPSTF and ACOG call for more robust evidence for the currently undefined optimum dose/type of exercise for PD (ACOG, 2020; Dipietro et al., 2019; O'Connor et al., 2019; USPSTF, 2019).

# Subgroup analyses

Five subgroup analyses based on the PICOS criteria (excluding the Comparison [C] and Study design [S] criteria addressed by sensitivity analyses) tested differences between exercise and control groups on PD scores post-intervention across various participant and intervention characteristics, comparisons, or outcome measures used. An additional subgroup analysis tested differences between exercise and control groups on PD scores at follow up. Forest plots were inspected for outliers seriously influencing the exercise effect. All analyses considered that  $\geq 5$ comparisons provide more accurate results (Borenstein et al., 2009). The Chi<sup>2</sup> statistic for heterogeneity tested subgroup differences. Finally, risk of difference (RD) computation examined dropout differences between interventions and controls.

# Results

#### Results of the search

The PRISMA flow diagram presents study selection and reasons for exclusion (see Figure 1). A total of 285 studies were identified after duplicate removal. Following title/abstract review, 64 studies were selected for full-text review of which 50 were excluded. To this extent, fourteen trials with sixteen comparisons and 2.025 participants were included in our meta-analysis (Daley et al., 2015b; Daley et al., 2008; Forsyth et al., 2017; Haruna et al., 2013; Huang et al., 2011 [three-armed]; Mohammadi et al., 2015 [three-armed); Norman et al., 2010; Perales

et al., 2015; Robichaud, 2008; Robledo-Colonia et al., 2012; Shelton, 2015; Surkan et al., 2012; Vargas-Terrones et al., 2019; Yang & Chen, 2018). Eligible trials were conducted in eight countries (see Table 1) and were published in peer reviewed academic journals except from two unpublished Theses (Robichaud, 2008; Shelton, 2015).

Characteristics and risk of bias of included studies

# **Participants**

Participants' depressive symptom severity at baseline was mild-moderate in nine trials (Haruna et al., 2013; Huang et al., 2011; Mohammadi et al., 2015; Norman et al., 2010; Perales et al., 2015; Shelton, 2015; Surkan et al., 2012; Vargas-Terrones et al., 2019; Yang & Chen, 2018) and moderate-severe in five trials (Daley et al., 2015b; Daley et al., 2008; Forsyth et al., 2017; Robichaud, 2008; Robledo-Colonia et al., 2012). Also, participants at baseline were pregnant women in five trials (Huang et al., 2011-[1<sup>st</sup> intervention]; Mohammadi et al., 2015-[1<sup>st</sup> intervention]; Perales et al., 2015; Robledo-Colonia et al., 2012; Vargas-Terrones et al., 2019) and postpartum women in the remaining trials. Details are presented in Table 1. Additional information regarding participants' profiles (e.g., perinatal age) can be found in Appendix 2. *Interventions* 

Five trials employed aerobic exercise modalities at moderate intensity for  $\geq$  150min/week; these modalities included pram walking (n= 2), walking and various aerobic activities, dance activities, or aerobic and strength training (average dose: 52.50min/session, 3.50sessions/week, 168.00min/week, 20.04weeks; median session attendance 69.30%) (Daley et al., 2008; Forsyth et al., 2017; Perales et al., 2015; Robledo-Colonia et al., 2012; Vargas-Terrones et al., 2019). Three trials employed aerobic exercise at low-moderate or moderate intensity for 90min/week (n= 2; mainly walking) or at moderate intensity for 120min/week on

average (3-5sessions/week X 30min) (Daley et al., 2015b; Robichaud, 2008; Shelton, 2015); one trial employed aerobic + stretching exercise for 45min/week (≥ 3sessions/week X 15min; body movements on sitting/standing position) (Yang & Chen, 2018); two trials used strength and aerobic training at moderate intensity for 60min/week or aerobic exercise with undefined type/intensity for 360min/week (Haruna et al., 2013; Norman et al., 2010) (average dose for the above six trials: 40.71min/session, 3.29sessions/week, 130.71min/week, 15.43weeks; median session attendance 77.2%).

Another trial used counseling/planning for diet modifications and 150min/week of exercise at moderate-vigorous intensity (not reported if aerobic) (Surkan et al., 2012). Also, one trial employed low intensity stretching and breathing for 75min/week for pregnant (1st intervention) or for postpartum women (2<sup>nd</sup> intervention) (Mohammadi et al., 2015). Finally, one trial employed counseling for diet plus exercise-(not otherwise defined) for pregnant (1st intervention) or postpartum women (2<sup>nd</sup> intervention) (Huang et al., 2011). Individual trial descriptions (14 RCTs / 16 comparisons) following the above order are presented in Table 1.

Additional information regarding the implementation of the reviewed trials indicated that eight trials (Daley et al., 2015b; Daley et al., 2008; Haruna et al., 2013; Norman et al., 2010; Perales et al., 2015; Robichaud, 2008; Robledo-Colonia et al., 2012; Vargas-Terrones et al., 2019) and two trials (Forsyth et al., 2017; Mohammadi et al., 2015) reported that their participants attended on average > 50% (median: 81%) and < 50% (median: 33%) of the exercise sessions, respectively. Also, seven trials delivered individual exercise (Daley et al., 2015b; Daley et al., 2008; Huang et al., 2011; Mohammadi et al., 2015; Robichaud, 2008; Surkan et al., 2012; Yang & Chen, 2018) and five trials group exercise (Haruna et al., 2013; Norman et al., 2010; Perales et al., 2015; Robledo-Colonia et al., 2012; Vargas-Terrones et al., 2019); only the latter five trials were supervised. Four trials employed pedometer devices (step counters) in the exercise interventions (Daley et al., 2015b; Daley et al., 2008; Shelton, 2015; Surkan et al., 2012). The average exercise dose across all the reviewed trials (14 RCTs / 16 comparisons) was 41.92min/session, 3.31sessions/week, 136.07min/week, 18weeks; median session attendance 69.40%; intensity was mainly moderate. Details are presented in Table 1.

# **Comparisons**

In seven trials controls were assigned to usual perinatal care that did not involve exercise conditions (Daley et al., 2015b; Forsyth et al., 2017; Mohammadi et al., 2015; Norman et al., 2010; Perales et al., 2015; Robledo-Colonia et al., 2012; Surkan et al., 2012). The remaining seven trials assigned controls to usual perinatal care combined with exercise conditions including wait-list to exercise participation (Haruna et al., 2013; Robichaud, 2008), wait list to receive exercise consultancy (Daley et al., 2008), advice to follow doctor's exercise guidelines (Vargas-Terrones et al., 2019), exercise plus diet counseling (Huang et al., 2011), informational material for exercise (Yang & Chen, 2018) or instructions to record daily steps via study pedometers plus wait list to exercise (Shelton, 2015). Details are presented in Table 1.

## Outcomes

Depressive symptomatology was the primary outcome measure in all but four trials (Haruna et al., 2013; Huang et al., 2011; Norman et al., 2010; Yang & Chen, 2018). Nine trials (Daley et al., 2015b; Daley et al., 2008; Forsyth et al., 2017; Haruna et al., 2013; Mohammadi et al., 2015; Norman et al., 2010; Robichaud, 2008; Shelton, 2015; Yang & Chen, 2018) used the Edinburg Postpartum Depression scale (EPDS) (Cox et al., 1987), four trials (Perales et al., 2015; Robledo-Colonia et al., 2012; Surkan et al., 2012; Vargas-Terrones et al., 2019) the Centre for Epidemiologic Studies Depression (CES-D) scale (Devins et al., 1988), and one trial (Huang et al., 2011) the Beck Depression Inventory (BDI) (Beck & Steer, 1993). All outcomes were selfreported and included continuous measures, with higher numbers indicating more severe depressive symptoms. Only two trials undertook a clinical diagnosis of depression (Daley et al., 2015b; Forsyth et al., 2017). Relevant details are presented in Table 1. Additional information regarding recruitment and outcome time points with respect to perinatal age are presented in Supplemental Table S1.

# Study design

All trials were RCTs. Five trials (Daley et al., 2015b; Forsyth et al., 2017; Mohammadi et al., 2015; Norman et al., 2010; Vargas-Terrones et al., 2019) employed follow up outcome measures, on average 3 months after the intervention completion (see Table 1). Two trials were unpublished Theses (Robichaud, 2008; Shelton, 2015).

# Assessment of risk of bias

Eight trials (57%) received a score of  $\geq$  6 on the PEDro scale indicating lower risk of bias (Daley et al., 2015b; Forsyth et al., 2017; Haruna et al., 2013; Mohammadi et al., 2015; Perales et al., 2015; Robledo-Colonia et al., 2012; Vargas-Terrones et al., 2019; Yang & Chen, 2018). Six trials (43%) received a score < 6 indicating higher risk of bias (Daley et al., 2008; Huang et al., 2011; Norman et al., 2010; Robichaud, 2008; Shelton, 2015; Surkan et al., 2012). Relevant details are presented in Table 2. Cohen's Kappa coefficient was .64 indicating substantial interrater reliability (Landis & Koch, 1977) on the PEDro scale.

## Synthesis of results

Based on pooled results from 14 RCTs (16 arms), exercise in comparison to controls demonstrated a statistically significant, small overall effect on post-intervention scores of PD (SMD = -.21, 95% Confidence Intervals [CI] -.31, -.11, p = .0001) with low/non-significant

heterogeneity (Q = 17.82,  $I^2 = 16\%$ , p = .27). Details are presented in Table 3 and in Figure 2. Visual inspection of the funnel plot displayed no indications of asymmetry (see Figure 3), and both the Egger and the Begg and Mazunbar algorithms were non-significant (Egger: intercept - .68, p = .41; Begg-Mazunbar Kendall's tau: tau -.12, p = .53). However, the fail and safe criterion (5K + 10; in our study: 5 X 16 + 10 = 90 comparisons) detected marginally significant publication bias, as the algorithm indicated that 89 studies would be required to nullify the significance of the overall effect. Trim and fill analysis on both sides of the plot was subsequently computed but added no study, suggesting no publication bias for the overall effect.

According to our sensitivity analyses, the small overall effect of exercise on postintervention PD scores increased in trials with lower risk of bias (SMD = -.24, 95% CI -.43,-.04, p = .02;  $I^2 = 46\%$ , p = .06), in trials with controls that did not involve exercise conditions (SMD = -.28, 95% CI -.45, -.10, p = .002;  $I^2 = 41\%$ , p = .11), and in trials with moderate intensity aerobic exercise for  $\ge 150$ min/week (SMD = -.43, 95% CI -.64, -.21, p < .0002;  $I^2 = 18\%$ , p = .35). Heterogeneity was low/non-significant ( $I^2 = 18\%$  -46\%). Results are presented in Table 3.

Subgroups analyses examined if exercise decreases PD scores post-intervention across various participant/intervention characteristics, comparisons, or outcomes used. Particularly, exercise compared to controls showed (a) small-moderate antidepressant effects when exercise was delivered in groups or in pregnant women, when the CES-D/BDI outcomes were employed and when participants had moderate-severe depressive symptoms or sedentary/insufficient active lifestyle at baseline, or when they attended > 50% of exercise sessions; (b) small antidepressant effects when exercise was delivered individualized or in postpartum women, and when participants had mild-moderate depressive symptoms or undefined physically active lifestyle at baseline; (c) zero effect when participants attended < 50% of the exercise sessions, and a small

non-significant antidepressant effect when the EPDS outcome was employed. The latter effect increased 2-fold and reached significance after removing two non-aerobic outliers (Mohammadi et al., 2015; Yang & Chen, 2018). In an additional subgroup analysis, exercise compared to controls showed a statistically significant small antidepressant effect on PD scores measured at follow up (on average 3 months after the intervention completion). Heterogeneity was low/non-significant (I  $^2 = 0\%$  -50%) in all subgroup analyses.

Subsequently, we performed comparisons between the different subgroups described above. The analysis showed that when compared to controls exercise showed (a) significantly larger antidepressant effects for participants attending > 50% of the exercise sessions, than participants attending < 50%; (b) significantly larger antidepressant effects for participants showing a sedentary/insufficiently active lifestyle at baseline, than participants with unidentified physical activity levels at baseline; (c) marginally insignificant larger antidepressant effects when exercise was delivered in groups, than when exercise was delivered individually (p = .06). Results are presented in Table 4.

Dropouts were 15.07% in the exercise interventions and 13.31% in the control conditions after excluding one outlier with 39.72% and 41.53% dropouts in the interventions and controls, respectively (Surkan et al., 2012). No differences between exercise and controls were found in the number of dropouts (RD = -.002, 95% CI -.049, .040, p = .919;  $I^2 = 36.12$ , p = .08). Also, no differences between interventions and controls in the number of dropouts were found among pregnant women (RD = -.003, 95% CI -.133, .072, p = .560; 381 I<sup>2</sup> = 67.50%, p = .02) or among postpartum women (RD = -.020, 95% CI -.027, .066, p = .409; I<sup>2</sup> = 0%, p = .533). In addition, no differences between pregnant and postpartum women were found in the number of dropouts

either in the interventions or controls (RD = -.032, 95% CI -.071, .006, p = .097;  $I^2 = 0\%$ , p = .824).

# Hedges' g corrections

Computations of Hedges' g correction, which prevents overestimation of an effect-size for < 20 comparisons such us our data set, did not change the effects or heterogeneity levels across all the analyses. Presenting SMDs is in concordance to previous meta-analyses in the field and in support of transparent graphic/numeric cross reading for clinicians/researchers.

#### Discussion

## The overall antidepressant effect of exercise

To our knowledge, this is the first meta-analysis to focus on RCTs examining whether exercise interventions improve PD symptoms in perinatal women recruited and exercised through perinatal health services. Findings showed that exercise was associated with a significant small overall effect on PD symptoms (SMD = -.21). In previous reviews, the effects of exercise on PD symptoms ranged from .22 to .81 and appeared to be larger than our effect. However, previous meta-analyses included a number of quasi-RCTs and/or observational studies or trials with mindful activities (e.g., yoga). Instead, the current study focused on RCTs because they represent the gold standard of evidence (Schulz et al., 2010), and examined exclusively exercise interventions because they show distinct differences to mindful activities (La Forge, 2005).

In addition, previous meta-analyses included a number of trials for perinatal women attending exercise programs in various community settings (e.g., Carter et al., 2019; Davenport et al., 2018; Nakamura et al., 2019). To address this gap, we reviewed RCTs with samples from exercise interventions provided through perinatal health services; this approach revealed that such interventions show low attrition and significant antidepressant effects in routine practice settings. Consequently, the findings of the current study provide researchers/clinicians with data to support future implementation of exercise trials or interventions in those specific settings. *Sensitivity analyses* 

In the first sensitivity analysis, the overall antidepressant effect of exercise increased in lower risk of bias trials, suggesting greater treatment efficacy in higher design quality. Importantly, lower risk of bias increases the odds of recording the true treatment effects, whereas higher risk of bias may overestimate treatment effects (Moher et al., 1998; Schulz, 2001; Schulz et al., 1995). This finding receives additional merit because the risk of bias tool employed in the current study was exercise specific and included challenging methodological criteria such as < 15% dropouts.

In the second sensitivity analysis, the overall effect of exercise increased in trials with controls that did not involve exercise conditions. Similarly, a recent meta-analysis recorded significant antidepressant effects for exercise vs. non-exercise comparators in RCTs for adult patients with a referral or clinical diagnosis of major depression (Morres et al., 2019a). In contrast, exercise embedded in controls decreases also depressive scores, and may mask the true effects of exercise interventions (Schuch et al., 2017).

In the third sensitivity analysis, the overall effect further increased in trials delivering aerobic type exercises at a dose of  $\geq$  150min/week at moderate intensity. This finding sheds some light on the inconclusive issue of the optimum type/dose of exercise for PD. Specifically, the ACOG (2020) Committee Opinion in 2020 reports that exercise can be an essential factor in the prevention of postpartum depression, but also calls for research on the optimum exercise dose. Similarly, the ACSM review and the USPSTF Recommendation Statement report lack of evidence for the causal exercise effects on lower PD symptoms and call for research on the optimum type/dose of exercise (Dipietro et al., 2019; O'Connor et al., 2019; USPSTF, 2019). Researchers may thus consider that aerobic exercise at a dose of  $\geq$  150min/week at moderate intensity improved PD symptoms in this study.

The same dose of aerobic exercise during pregnancy can decrease the risk of postpartum depression WHO (WHO, 2020). Similarly, meta-analyses suggest that aerobic exercise decreased postnatal (Pritchett et al., 2017) or prenatal/postnatal depressive symptoms (Davenport et al., 2018). In the latter study, moderate intensity exercise interventions (including aerobic exercises) for  $\geq$  150min/week decreased PD scores (Davenport et al., 2018). Given the link of aerobic exercise with lower PD symptoms, it is encouraging that the simple/self-operated aerobic exercise of walking is widely selected by mental health patients (Morres et al., 2019b; Sørensen, 2006) attributable to their low physical competence (Van de Vliet et al., 2002a; Van de Vliet et al., 2002b).

Finally, it is interesting to note that the SMDs across the three sensitivity analyses ranged from .24 to .43. These effect sizes appear to be clinically meaningful because treatment efficacy corresponding to an SMD of  $\geq$  .24 suggests clinically relevant alleviation in depressive disorders (Cuijpers et al., 2014).

#### Subgroup analyses

# Exercise and depressive severity

The beneficial effects of exercise on PD symptoms were small among women with mildmoderate PD symptoms and small-moderate among women with moderate-severe PD symptoms. Importantly, severe PD displays more serious risks to children's development than milder depression (Slomian et al., 2019). Risks include prematurity, low birth weight, intrauterine growth restriction, cognitive, behavioral, and emotional issues during childhood (Andersson et al., 2004a; Bonari et al., 2004; Dayan et al., 2002). Severe PD is also linked to high-risk health behaviors, partner or sexuality problems (Andersson et al., 2004b; Faisal-Cury et al., 2013; Zuckerman et al., 1989), suicidal ideation and infanticide or self-harm thoughts (Mangla et al., 2019; Paris et al., 2009; Pope et al., 2013). Interestingly, we found that exercise was also effective in samples with mild-moderate PD symptoms. Given that the majority of these samples had mild PD symptoms corresponding to non-clinical levels, it is seen that exercise does not display floor effects. In line, exercise has previously improved depressive symptoms among nonclinical adult populations (Rebar et al., 2015).

## Exercise in pregnant and in postpartum women

In light of the ACOG (2020) report that PD symptoms occur from gestation and throughout the first 12 months after delivery, the samples of trials in this study were treated as a whole. However, we performed a subgroup analysis to explore if exercise brings about different antidepressant effects on pregnant and postpartum women. Exercise showed small and small-moderate reductions in PD symptoms among pregnant and postpartum women, respectively; no between-group differences were found, however, the effect of exercise on pregnant women tended to be larger (p = .11). The antidepressant effects of exercise were combined with low dropouts and with satisfactory and profound consistency in pregnant and postpartum women, respectively. Significant antidepressant effects combined with low dropouts and high consistency were also recorded by a recent meta-analysis for exercise in clinically diagnosed major depressed adult patients (Morres et al., 2019a). Overall, findings suggest the promising role of exercise in ameliorating PD symptoms among pregnant or postpartum women in perinatal health services. *Group or individualized exercise* 

Group and individualized exercise led to small-moderate and small decreases in postinterventions scores of PD symptoms, respectively. Differences between the effects were marginally insignificant (p = .06). As only group exercise was supervised, the small-moderate effect could be attributed to social contact with supervisors/peers. Previous meta-analyses have also found larger reductions in PD symptoms for group and/or supervised exercise than for individual and/or unsupervised exercise (Davenport et al., 2018; McCurdy et al., 2017). Increased social support appears to be an exercise facilitator, decreased social support an exercise barrier (Albright et al., 2006), whereas lack of social support is related to developing PD (Hetherington et al., 2020) or more severe depression (Hetherington et al., 2018; Martini et al., 2015). Noteworthy, 80% of the reviewed trials in this sub-analysis used exercise-only interventions, which seem to be more effective than exercise co-interventions (e.g., exercise plus diet) (Carter et al., 2019; Davenport et al., 2018).

#### Exercise attendance rates

Exercise revealed a small-moderate antidepressant effect on women attending > 50% of the exercise sessions (median: 81%) and zero effect on women attending < 50% of the exercise sessions (median: 33%). We found marginally significant differences between the effects (p = .05). To this extent, only frequent participation in exercise seems to alleviate PD symptoms. Similarly, the ACOG (2020) Committee Opinion suggests exercise on most or all days of the week for potential prevention of postpartum depression.

Exercise for women with sedentary/insufficiently lifestyle or unidentified physically active lifestyle

The beneficial effect of exercise on PD scores was moderate on women with sedentary/insufficiently active lifestyle at baseline and small on women with unidentified

physical activity at baseline. The former effect was significantly larger than the latter and stemmed from aerobic interventions combined with behavioral modification techniques or exertion tools. Such interventions seem vital, especially since sedentariness correlates to PD, worse mood and depression/somatic symptoms, which they interfere with social/daily activities (Poudevigne & O'Connor, 2006). In a recent meta-analysis exercise displayed small nonsignificant relief in PD symptoms among previously sedentary perinatal women, but comparisons included only one trial (Davenport et al., 2018).

## *Exercise and depression outcome measures*

Exercise showed significant small-moderate and non-significant small antidepressant effects, respectively, when the CES-D/BDI and the EPDS outcomes were employed. The latter effect increased 2-fold and reached significance after removing the non-aerobic trials (n= 2). Due to self-report, these outcomes measures are cost- and burden-effective (Rosenman et al., 2011), and diminish error variance of clinician ratings by preserving the same items across individuals (Cuijpers et al., 2010). However, response bias (e.g., misunderstanding) may decrease sensitivity to change due cognitive deficits in depression (Shenal et al., 2003). The EPDS is the most widely used psychometric for PD symptoms (Guedeney et al., 2000; Murray & Carothers, 1990), whereas the CES-D is not particularly specific to recording depressive symptoms (McQuaid et al., 2000).

# The antidepressant effects for exercise at follow up

Exercise revealed a sustained relief in PD symptoms measured at follow-up, on average 3 months after the intervention completion. This finding suggests enduring effects for exercise. Based on available data from trials reviewed in this sub-analysis, women were exercising for > 150min/week at intervention completion (Daley et al., 2015b; Daley et al., 2008). Sustained relief in PD symptoms on average 3 months after the intervention completion seems to be a crucial finding given the often-recurrent course of depression. For example, many new mothers (39%) experience severe depression at 3.5year follow-up period with longer depressive episodes and more negative events in daily life (Vliegen et al., 2014; Vliegen et al., 2013). Importantly, daily life physical activity predicts decreased symptoms of depression. Particularly,  $\geq$  150min/week of objectively measured moderate intensity physical activity predicted lower depression scores in a naturalistic study for clinically diagnosed major depressed adult outpatients (Morres et al., 2019c).

## Limitations

Certain aspects of this study should be considered when interpreting the findings. The first aspect is the small number of RCTs reviewed. However, this is the most commonly seen limitation in the field of exercise and depression; also, we reviewed exclusively RCTs with exercise interventions and samples in perinatal health services and, in addition, only one publication bias algorithm was marginally significant with subsequent trim-fill tests not adjusting the effect. Further, all but one sub-analysis included  $\geq$  5 comparisons for more precise results, the heterogeneity levels were low/non-significant suggesting treatment consistency, and the confidence intervals were mainly narrow in contrast to other studies (Daley et al., 2015a; Nakamura et al., 2019). In addition, most of the reviewed trials appeared to be of medium to high design quality, while previous meta-analyses reported including mainly low, low medium or medium quality trials (Carter et al., 2019; Davenport et al., 2018; Poyatos-León et al., 2017; Pritchett et al., 2017). It is also important to note that the current study evaluated risk of bias with an exercise specific tool with challenging criteria (e.g., < 15% dropouts), whereas previous meta-analyses employed non-exercise specific risk of bias tools. Given also the small data set in this

study, we computed Hedges' g corrections for < 20 comparisons and found no change for the effects or heterogeneity levels.

The second aspect of this study that warrants consideration involves the employment of various exercise interventions across the reviewed trials, such as posting out digital informational material for home-based individualized low intensity exercise, supervising group-based moderate-vigorous exercise or delivering face to face or phone counseling for exercise. However, considering that this meta-analysis recorded the effectiveness of ≥150min/week of moderate intensity aerobic exercise, further trials adopting relevant exercise interventions are needed to increase our confidence for the present findings. The third aspect of this study concerns the fact that the reviewed RCTs employed different outcome measures of PD symptoms, including the CES-D, which is not particularly specific to recording depressive symptoms (McQuaid et al., 2000). The employment of perinatal-specific depression instruments, such as the EPDS, would facilitate further synthesis of empirical evidence.

Some additional issues of this study should be also considered. Particularly, the lack of information on social contact time in our reviewed controls did not allow comparisons with interventions to trace potential imbalance and confounding influences. Equalizing between-group social contact may clarify if exercise per se improves scores of depression. Moreover, the reviewed trials in this study did not examine for side effects induced by exercise. Examining for side effects in future studies may provide clarifications concerning safety. Relevant examination needs to be conducted with standardized instruments to ensure firmer conclusions on the safety of exercise. However, the current study found low dropouts and no side effects or other adversities induced by exercise, whereas the AGOC (2020) reports exercise is typically safe for perinatal women. Similarly, a recent meta-analysis found low dropouts and minimum side effects

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induced by exercise among clinically diagnosed major depressed adult patients in mental health services (Morres et al., 2019a).

A final issue concerns the generalizability of findings. First, we reviewed only 14 RCTs including two RCTs with clinically diagnosed PD women. However, the small number of exercise trials in perinatal health services and the scarce samples with a clinical diagnosis of PD represents a typical limitation in the field. Also, this is the first meta-analysis to review exclusively RCTs examining the effects of exercise on PD symptoms in perinatal women in perinatal health services. Second, available information showed that 32% of the women identified as eligible to participate by our reviewed RCTs were reluctant to entering into studies. Further, dropouts from ongoing participation in exercise interventions were 15.07% and did not differ to controls (13.31%), whereas pregnant and postpartum women revealed comparably low dropouts. Similar attrition was found in a meta-analysis of exercise for clinically diagnosed major depressed patients, as 35% of eligible participants were reluctant to entering into studies and < 15% dropped out (Morres et al., 2019a). These attrition numbers appear to be rather low in light of the high time/effort demands of exercise (Turk et al., 1984) or the actual barriers in the perinatal period (e.g., childcare). Despite the relatively low attrition rates, theory-driven recruitment and exercise interventions may consider individual preferences/needs to further decrease attrition from exercise trials for PD symptoms. Satisfaction of individual preferences/needs for exercise is suggested by exercise-depression guidelines (National Institute for Clinical Excellence [NICE], 2009; Ravindran et al., 2016) and linked to low attrition and large antidepressant effects in clinically diagnosed major depressed patients (Morres et al., 2019a). Also, higher odds ratios for participation in exercise are given by intrinsic motives involving satisfaction of personal preferences (e.g., exercise for joy) rather than by extrinsic

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motives (e.g., exercise for health gains) (Sørensen, 2006). In addition, perinatal women report various intrapersonal barriers to exercise participation including lack of time, too busy, lack of energy, tiredness, or various medical conditions such as discomfort or pain (Evenson et al., 2009). Strategies modifying these barriers may lead to higher adherence to exercise (Evenson et al., 2019). In line, the promotion of pedometer devices (step counters) may help perinatal women meet physical activity guidelines given that pedometers enable both clinician- and selfmonitoring of objectively measured data related to physical activity (Battle et al., 2015). Finally, raising awareness regarding the benefits of exercise during the perinatal period, could eventually lead women to adopt exercise as a well-being strategy.

## Implications for research and practice

Researchers/clinicians could consider that exercise for an average of 136.07min/week at moderate intensities (41.92min/session, 3.31sessions/week, 18weeks), which falls within the range of physical activity recommended by ACOG (2020), led to a significant improvement in PD symptoms. Moreover, moderate intensity aerobic exercise for  $\geq$  150min/week, in particular for an average of 168.00min/week, further improved PD symptoms; this improvement was both statistically significant and clinically meaningful. Thus, the dose of  $\geq$  150min/week of moderate intensity aerobic exercise should attract further attention in treating PD symptoms. In addition, group/supervised exercise delivery formats, and frequent attendance (>50%) of exercise programmes, emerged as beneficial features.

Interestingly, exercise was effective among samples with various severities in PD symptoms including PD symptoms corresponding to non-clinical levels. To this extent, exercise showed no floor effects and emerged as a potentially important tool to maintain non-clinical levels of PD symptoms or prevent possible deterioration. The lack of floor effects represents a good reason as to why exercise should be promoted to non-clinical adult populations to prevent potential deterioration in PD symptoms.

Researchers/clinicians should also be aware that further confidence for the study findings is derived from indications that exercise showed to be acceptable, with sustainable and consistent treatment effects, which increased in lower risk of bias. In addition, exercise was effective in common/challenging perinatal health services users including women with previously sedentary/insufficiently active lifestyle across the full span of PD symptom severities. Notwithstanding the small number of RCTs and the scarce number of clinically diagnosed PD samples reviewed, the findings of this study highlight that exercise may effectively support routine practice in the treatment of PD symptoms. However, more robust RCTs with clinically diagnosed PD samples and systematic examination for side effects are needed for firmer conclusions.

# Conclusions

This is the first meta-analysis to review exclusively RCTs for the effects of exercise on PD symptoms in perinatal women recruited via perinatal health services. Exercise at mainly moderate intensities for an average of 136.07min/week (41.92min/session, 3.31sessions/week, for 18weeks) showed a significant small antidepressant effect on PD symptoms. This effect increased in RCTs with lower risk of bias or with moderate intensity aerobic exercise interventions delivered for an average of 168min/week (52.50min/session, 3.50sessions/week, 20weeks). Also, the effects of exercise were found to be significant across various settings, delivery formats, depressive symptom severities or outcome measures used. Findings support the beneficial role of exercise in PD symptoms, but systematic examination for potential side effects induced by exercise is essential to confirm current guidelines reporting that exercise is typically

safety in perinatal women. Findings also support the implementation of more exercise trials for clinically diagnosed PD, as only two relevant RCTs were tracked. Such RCTs could allow firmer clinical conclusions and should thus be prioritized, especially since PD is widely untreated, whereas exercise is typically safe in perinatal women and broadly preferred in mental health services.

## **CHAPTER IV**

# THEORETICAL BACKGROUND

# THE TRANSTHEORETICAL MODEL OF CHANGE IN THE PHYSICAL ACTIVITY DOMAIN

# Background

The Transtheoretical Model (TTM) of behaviour change was developed to integrate components of other theories of behaviour change into one widely applicable model. It synthesises many different theoretical and clinical aspects of psychotherapy and ultimately characterise how individuals make changes in their lives. Developed by Prochaska and DiClemente (1982), the TTM is a comprehensive model of change, theoretically derived and supported by empirical research. The TTM has been widely used in the treatment of addictive and/or problem behaviours (Casey et al., 2005). While originally focusing on smoking behaviour (Spencer et al., 2002), the stages of change component of this model has been tested with a wide range of behaviours, from individuals attempting to lose weight (Prochaska et al., 1992), stroke victims engaging in exercise (Garner & Page, 2005), cancer screening behaviours (Eiser & Cole, 2002), sexually transmitted diseases and/or pregnancy prevention (Horowitz, 2003) and dietary habits (Snelling & Adams, 2006). Through its basic components and constructs (e.g., stages of change, decisional balance and self-efficacy) it attempts to explain both how and why behaviour change occurs and through the appropriate processes of change how these changes can be aided.

#### **TTM constructs**

The TTM is consisted of three components relating to change: stages of change, processes of change, and levels of change. Prochaska and DiClemente (1982), integrated two additional components, self-efficacy and decisional balance, to determine transition and behaviour change. Although most researchers agree that that the TTM provides a foundation to accurately assess individuals' readiness for change and understand their progress and behaviour outcomes, it has also been subjected to criticism and its validity has been questioned.

# The stages of change

The stages of change (Table 5) are of major importance within the model (Dannecker et al., 2003). They were conceptualised as a series of phases an individual pass through (back and forth) during a behaviour change (Prochaska & Velicer, 1997). Each stage of change integrates intentional, behavioural and temporal aspects of behaviour change (Martin-Diener et al., 2004), which allows the model to explain the process of behaviour change (Table 6). For example, the model conceptualises components of behaviour change, such as the intention to be physically active, the actual state of being active or inactive and the "readiness" to change (Marshall & Biddle, 2001). The temporal nature of stages of change has been described by Prochaska and Marcus (1994, p.162) as "both stable and dynamic" meaning that individuals temporarily stay in a certain stage or move across stages of change according to circumstances.

The TTM had a significant influence on the way we think of change, and particularly, on the way we conceptualise addictive and problem behaviours, moving away from a linear circuit to instead describing change in a circular manner (Prochaska & DiClemente, 2005). Moreover, the TTM has reinforced us to change our language regarding change, proving to be less judgmental, such as describing resistant or unmotivated individuals as pre-contemplators or contemplators (Prochaska & DiClemente, 2005).

Some perceptions of the TTM have included a sixth stage called "termination". Termination's main condition is to complete self-efficacy to maintain the healthy behaviour with no temptation to relapse to the unhealthy behaviour (Prochaska & Velicer, 1997). While it was generally applied in cessation behaviours, such as quit smoking, concerns have been raised regarding its applicability for adoption behaviours (Prochaska & Marcus, 1994; Courneya & Bobick, 2000), for example, being physically active. According to Wankel and Hills (1994, p.117) "with respect to changing from a sedentary to an active lifestyle, it is questionable whether a true termination point is ever reached". Also, Nigg et al. (2002) supported that the termination stage is not typical for PA because individuals are always at risk for relapse and have to make conscious efforts to overcome inactivity.

## The processes of change

The processes of change were identified and described through the comparative analysis of 18 theories of psychotherapy and behaviour change (Table 7). Processes of change discuss personal strategies and techniques to influence cognitive, emotional and behavioural aspects as well as staying, progressing or regressing through the stages of change (Prochaska & DiClemente, 1982). They represent constructive elements of design, implementation and success of interventions (Biddle & Fuchs, 2009), by providing information on why and how movement through stages occurs. According to the TTM, successful behaviour change interventions "must be tailored to a person's current stage of change and make use of the appropriate processes of change." (Adams & White, 2003, p.106). Processes of change accumulated from personal experiences are labelled as experiential while those accrued from interaction with the environment are labelled as behavioural processes (Nigg et al., 2011).

*The experiential processes include*: i) consciousness raising: gathering information and increasing awareness about the causes and benefits of a certain behaviour. Accomplished through observations, confrontations, and searches in published materials, ii) dramatic relief: experiencing and expressing feelings about one's problematic behaviour and solutions for it.

Through emotional arousal it generates awareness of the problem. Common ways of initiating are through psychodrama or role-playing, iii) environmental re-evaluation: cognitive and affective assessment of how a personal habit affects one's social environment, for example through role modelling. This social re-appraisal is implemented through empathy training or watching documentaries, iv) social liberation: increasing social opportunities or alternatives especially for people who are relatively deprived or oppressed. These environmental opportunities signal the awareness of the problem and can be experienced through empowering or initiation of policy-interventions, v) self-re-evaluation: cognitive and affective assessment of one's self-image with and without a particular habit, for example being an active or an inactive person. This self-re-appraisal emphasises how desires, beliefs and feelings are changing with respect to self-image and can be achieved through value clarification, imagery and corrective emotional experiences.

*The behavioural processes include:* i) stimulus control: avoiding or countering stimuli that elicit problem behaviours. It is closely related to a more PA-friendly environment with less inactive temptations. It can be accomplished through avoidance techniques, environmental restructuring, and self-help groups, ii) helping relationships: being open and trusting about the problem behaviour with someone who cares. This personal support can be found through rapport building, therapeutic alliance, counselling and self-help groups, iii) counter conditioning: requires the learning of healthier behaviours that can substitute for problem behaviours, for example to cycle in a stationary bike while watching television. It includes relaxation, desensitisation, and positive self-statements, iv) reinforcement management: rewarding for accomplishing changes and reaching goals. Contingency contracts, overt and covert reinforcements, positive self-statements and group recognitions aiming at increasing the

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probability that healthier responses will be repeated, v) self-liberation: is both the belief that one can change and the continuous commitment to act on that belief. It can be accomplished through decision-making therapy, or public testimonies.

# Levels of change

Levels of change indicate that multiple conflicts at different levels may influence the problem behaviour. They represent where psychological problems are located within an individual, consciously and unconsciously. Five levels are described within the TTM model: i) symptom/situational problems, ii) maladaptive cognitions, iii) current interpersonal conflicts, iv) family/systems conflicts, and v) intrapersonal conflicts. The problem behaviour could appear as symptoms in response to a particular event or, it might be more complex as "symptoms may be supported by maladaptive cognitions, which create interpersonal conflicts" (Fromme, 2010, p.34). Health providers adopting the TTM are prompted to start at the symptom/situational level because change tends to occur more quickly when people are more conscious of their problems (Grimley et al., 1994). Psychological problems at one level are not experienced in isolation, meaning that change occurring to one level will reinforce changes on other levels as well (Grimley et al., 1994).

## Self-efficacy

Bandura (1977) defined self-efficacy as an important cognitive construct for explaining behaviour change. It highlights one's expectations around efficacy and determines if change is initiated, if change efforts continue and if change behaviours are sustained over time. Selfefficacy in the TTM is the belief that one is capable of making change. Change requires that one is ready, willing, and efficacious, thus, self-efficacy is important for motivation and commitment to change. According to Prochaska et al. (2004), individuals experience the greatest increase in self-efficacy during the action and maintenance stages. Research has shown the importance of this construct for predicting change for various behaviours such as sexual health screening (Banikarim et al., 2003), drunk driving (Freeman et al., 2005), physical activity (Kim, 2004), and sexual offending (Pollock, 1996). Marshall and Biddle's (2001) meta-analysis validated the hypothesis that self-efficacy increases from less active to more active stages of change, but not in a linear manner.

# **Decisional balance**

Decisional balance refers to an individual's weighing of the pros and cons of making change. Research has demonstrated a link between stages of change and decisional balance. Specifically, in precontemplation, the cons of changing outmatch the pros. Then, as individuals are moving to more advanced stages of change, the balance is switched and the pros of changing steadily increase (Prochaska & Velicer, 1997). Studies have found links among decisional balance, change related behaviour and stages of change in various populations (e.g., Chae et al., 2010; Luszczynska et al., 2011; Waterman et al., 2010). Prochaska and Velicer (1997) stated that considering the pros of changing is more effective than focusing on the cons of not changing in helping individuals to make changes. In a meta-analysis assessing PA and exercise interventions based on the TTM, Marshall and Biddle (2001) found that the pros of being active were increased from the least active stages of change to the most active stages of change while the cons decreased accordingly, as predicted by the TTM.

#### Validity of the TTM

The construct validity of the TTM has been shown across 48 different health behaviours including PA and exercise (Hall & Rossi, 2008). Hellsten et al. (2008), demonstrating data from nine studies, concluded that the algorithm of the stages of change was significantly related to

self-report and objective measures of PA. Moreover, Marshall & Biddle's (2001) meta-analysis including 71 TTM studies, and a review of several cross-sectional studies (Armitage, 2009) reinforced the model's construct validity for PA and exercise. Several studies revealed, across a variety of samples, that individuals in more active stages demonstrated higher levels of exercise and PA; with samples including adolescents, college students, adults, middle-aged females and older adults (Calfas et al., 1994; Emmons et al., 1994; Hausenblas et al., 2003; Hellman, 1997; Lee et al., 2001; Pinto & Marcus, 1995; Wyse et al., 1995).

#### Advantages of the TTM

Advantages of the TTM compared to other behaviour-change theories refer to its adaptability and practicality in a plethora of health behaviours (Ashworth, 1997; Prochaska, 2008; Smedslund, 1997). Cost-effectiveness and ease of its implementation and measurement was highlighted by Laforge et al. (1999) as another advantage. Additionally, as Kreuter et al. (2000) stated, the best term to describe the stage of change approach is "stage-matched" instead of "tailored". This term refers to the principle of "audience segmentation" (Armitage, 2009) expressed by the categorisation into stages contrary to a personalised adaptation. Thus, researchers can design interventions suitable to the needs of people that belong to a certain stage of change (Reed, 1999). That could potentially lead to a better intervention efficiency and higher retention rates (Carron et al., 2002).

Regarding the field of PA behaviour, one of the TTM's major contributions is the interaction between intention and behaviour (Buxton et al., 1996). According to Nigg et al. (2002, p.321), the synergy between intention and behaviour "leads to a broader range of outcomes of the behavioural change process that would normally not be detected with other approaches". For example, within the TTM, behaviour change would be detected when an
individual would slightly change his/her focus of intention for behavioural change moving from contemplation to preparation.

## Limitations of the TTM

According to Bandura (1997), human behaviour is too complex to be described by a set of stages. Bandura (1997) has argued that a genuine set of stages should possess qualitative differentiation among its components accompanied by an invariant and no reversible sequence of change. However, according to Smedslund (1997), the TTM is considered as conceptually and logically valid even beyond any empirical validation.

Culos-Reed et al. (2001), explained that in order to describe the complexity of human behaviour, a stage model is required to be more flexible and realistic than the one declared by Bandura (1997), for example, incorporating regression. Culos-Reed et al. (2001) suggested three limitations regarding the TTM. First, the stages of change are not empirically confirmed as a robust construct by applied research. However, the stages of change have been originated from empirical research (Prochaska & DiClemente, 1982) and have been validated up to a point for exercise by several studies (Cardinal & Sachs, 1996; Cardinal et al., 2002; Hausenblas et al., 1999; Marcus et al., 1992; Wyse et al., 1995;). Second, Culos-Reed et al. (2001) supported that the relationship between the processes of change and the stages of change has not been undoubtedly proven. However, according to Nigg et al. (2002), the relationship between the processes of change and the stages of change clearly identifies the use of mediators that are important for stage progression. Third, according to Culos-Reed et al. (2001) the TTM is mostly descriptive than explanatory. Sutton (1996) and De Bourdeaudhuij (1998), while supporting this view, suggested that the model should be considered as a prescriptive one, useful for designing interventions to help people change. Another criticism is that the TTM does not address any

moderator variables such as gender, age or ethnicity. However, such variables can be considered accordingly in research analysis.

Concluding, a constructive way forward would be trying to evaluate any limitations of the model and attempt to overcome or deal with them while taking advantage of its strong and effective elements within applied research.

## Studies investigating the effectiveness of TTM-based interventions

The effectiveness of TTM constructs in assessing PA behaviours has been investigated in a plethora of studies.

Adams and White (2003) conducted a comprehensive review of 16 TTM-based PA promotion interventions. Results revealed the efficiency of stage-matched interventions and their superiority compared to other methods. Specifically, in the short term ( $\leq 6$  months), the majority (73%) of the intervention groups were more effective compared to the control groups (p < .05), demonstrating increases in PA levels or stage progression compared to their baseline measurements. Regarding long term effects (> 6 months), results from seven interventions revealed increases in PA levels in the intervention groups (70%) compared to their baseline measurements. Intervention methods included interview counselling, written materials or a combination of both. The intervention group was compared to a group that did a non-stagematched intervention in most of the studies. However, it is important to mention that most studies included worksite or patient samples and were conducted exclusively in the USA and the UK, which limits their generalisability.

Another review conducted by Hutchison et al. (2009) to critically examine how the TTM has been applied to develop PA behaviour change interventions and to determine whether these TTM-based interventions were effective in promoting PA behaviour change, reported similar

results. The review included 24 PA interventions from 1996 to 2005 based on the TTM, 21 of which were randomised controlled trials (RCTs). In the short term ( $\leq 6$  months), 75% of the 24 studies were significantly more effective than the control conditions in stage of change progression, PA levels, or both. In the long term ( $\geq 6$  months), 25% of the eight studies were significantly more effective than the control conditions, which pointed out the potential difficulty in achieving long-term beneficial results.

Lipschitz et al. (2015) examined potential longitudinal differences in the application of the TTM behaviour change constructs in maintainers (who reached and maintained exercise guidelines), relapsers (who reached guidelines and then regressed), and non-changers (who did not reach guidelines). Results from two population-based TTM-tailored randomized trial intervention groups targeting exercise behaviour (N= 1050) were pooled, and analyses examined differences in TTM constructs between the three groups at baseline, 12 months, and 24 months. Findings demonstrated that relapsers tended to use TTM variables in a similar way with maintainers with the exception of self-efficacy, consciousness raising, and most behavioural processes of change, at 24 months. Non-changers used all TTM variables less than maintainers at almost every time point. Findings indicated that relapsers remained more active than nonchangers in terms of using the processes of change. Also, poor response to interventions (nonchangers) may be predicted by low baseline engagement in change processes. Although relapsers returned to physical inactivity, their overall greater use of TTM constructs indicated that their effort to change was better than those of the stable non-changer group. Authors suggested that future research could focus on treatment engagement strategies to help the stable non-changers to initiate change and to help relapsers to maintain treatment accomplishments.

A small number of studies examined the TTM components regarding PA or exercise among pregnant women or young mothers are limited.

More specifically, Fahrenwald et al. (2003), in their descriptive correlational study examined the relationship of TTM constructs and PA behaviour among postpartum women (N = 30) receiving assistance from the Women, Infants, and Children (WIC) programme. The examined constructs were PA behaviour pros and cons, decisional balance, self-efficacy, and processes of behaviour change. Significant relationships were found between stage of behaviour change and two PA energy expenditure indices, daily minutes of moderate to vigorous PA, cons, decisional balance, and self-efficacy. According to the results, the use of the 10 processes of change differed by stage of change. Pros to PA included a sense of accomplishment, increased strength, stress relief, and getting in shape after pregnancy. Cons included fatigue, childcare, and cold weather. Researchers supported the TTM as relevant to WIC mothers and suggested strategies to increase PA in this population.

Jones et al. (2013), assessed the PA levels among Western Australian mothers with young children who attend a playgroup. Factors such as self-efficacy for PA, social support for exercise, relevant socio-demographic correlates, and the stages of change construct within the TTM were assessed. Associations between PA status and exercise stage of change were found as well as associations between partner support and self-efficacy for PA. Authors highlighted the usefulness of the stages of change measure in identifying PA behaviour and design appropriate interventions for health promotion in playgroup settings.

Roozbahani et al. (2014) conducted a cross-sectional survey to examine the factors influencing the adherence to PA behaviour among postpartum women in Iran based on TTM constructs. Results demonstrated that the stages of change were the most powerful predictive

factor for PA behaviour in the model. Self-efficacy was the most powerful predictive factor of stages of change in PA behaviour. PA behaviour before pregnancy was the second most powerful factor in predicting current PA behaviour. Overall, the findings of this study supported the application of TTM in designing effective interventions to promote PA among Iranian postpartum women.

Haakstad et al. (2013) assessed women's readiness to become or remain physically active during pregnancy via the TTM constructs. According to the results, more than half of the participants (53%) were involved in regular exercise (stages 4 to 5) and about 33% reported engaging in some PA, but not regularly (stage 3). Results showed that receiving advice from health professionals to exercise during pregnancy increased the likelihood of being in stages four to five, while higher age, multiparity, pregravid overweight, unhealthy eating habits, pelvic girdle pain, and urinary incontinence were more prevalent with low readiness to change exercise habits (stages 1 to 3). Authors concluded that pregnancy may be a suitable period for the establishment of long-term PA habits and called for further research to investigate whether TTM-based interventions are effective in promoting PA during pregnancy.

Lewis et al. (2013) conducted a RCT to examine the efficacy of a PA intervention for the prevention of postpartum depression. Researchers allocated postpartum participants (N= 130; mean age= 31.54) with a history of depression or a maternal family history of depression to a six-month theory-based (Social Cognitive Theory & Transtheoretical Model of Change) PA intervention or a wellness/support control condition. Participants in the intervention group received individual phone-counselling for 24 weeks with the aim to increase their PA (moderate to vigorous intensity) to 30min/day for at least 5days/week. Participants in the control group received individual weekly phone-counselling for 24 weeks with the aim to be educated on

health/wellness topics. Results demonstrated that there were no differences in PA participation between the two groups. However, a higher level of PA participation was related to fewer depressive symptoms regardless of the study group (p < .05).

## Conclusion

The TTM is an influential model, providing useful information regarding behaviour change that can help to predict which individuals are ready to receive an intervention and access their needs throughout the change process. Literature suggests that behaviour change is directly related to one's readiness for change and can be described using the stages of change.

TTM-based interventions have been proved efficacious in promoting PA and exercise. However, results from long-term term follow-ups are missing. Knowledge about the stages of change towards PA among perinatal women is insufficient and currently only Lewis' et al. (2013) trial examined the efficacy of a TTM-based PA intervention for the prevention of depression among post-partum women.

Overall, the TTM is a useful framework, that could be enhanced and improved through more rigorous research and development. Suggestions for future research include the use of longitudinal intervention designs in more representative and diverse samples combined with standardised and validated assessment methods of PA.

### **CHAPTER V**

## **RESEARCH PAPER 2**

# EFFECTIVENESS OF A PERINATAL EXERCISE COUNSELLING INTERVENTION ON ALLEVIATING DEPRESSIVE SYMPTOMS: PRELIMINARY RESULTS OF A RANDOMISED CONTROL TRIAL

## Abstract

Perinatal depression is affecting approximately 16% of pregnant and 20% of postpartum women. Regular perinatal physical activity is considered a preventive factor for perinatal depressive symptoms. The primary aim of this single blinded, two-arm randomized controlled trial was to evaluate the effectiveness of an Exercise Counselling intervention compared to Perinatal Wellbeing Education on depressive symptoms of perinatal individuals recruited via obstetric care practices. Secondary aim was to examine the intervention's outcomes on anxiety levels and sleep quality. Twenty-five women were randomly assigned to the intervention group (N=12) or the active control group (N=13). Participants were provided with accelerometer devices to record their daily physical activity. Standardized questionnaires were administered at pre-, mid- and post-intervention. The intervention group reported significant improvements in symptoms of depression at mid- (p < .0001) and post-intervention (p < .0001) compared to the active control group. Anxiety symptoms were significantly lower for both mid- and post intervention, while sleeping difficulties were significantly lower for the intervention group compared to the active control group, but only at mid-intervention. Participants' total weekly physical activity was similar between the study groups at all measurement points. However, the intervention group engaged in significantly more minutes of moderate intensity and recreational physical activity at

mid- and post-intervention. The implemented Exercise Counselling intervention was beneficial for alleviating depressive symptoms, as well as decreasing anxiety levels and sleep disturbances. However, results indicated that exercise is not automatically related to reduced symptoms of depression and anxiety and that contextual factors associated with exercise parameters and domains (i.e., intensity of PA, domain-specific PA) are probably crucial to such effects. Larger randomized controlled trials with follow-up measurements are needed to ascertain these findings.

## Introduction

The perinatal period involves significant physiological and psychosocial challenges and adjustments, including modifications in individuals' social-status and decision making. Therefore, pregnant and postpartum women's mental health can be jeopardized (Biaggi et al., 2016). Perinatal depression (PD) has been identified as a public health problem, affecting approximately 16% of pregnant and 20% of postpartum women (WHO, 2017). Nevertheless, to a great extent it remains under-diagnosed or untreated (Goodman et al., 2014).

Under-diagnosis and lack of proper treatment of PD have been associated with short- and long-term adverse effects for the mother, the father, the child and the family. Common symptoms of PD include depressed mood, loss of interest, fatigue, changes in sleep or eating patterns, lack of concentration, feelings of worthlessness, and in severe cases recurrent suicidal ideation. As aforementioned, PD can affect all family members in a multilevel fashion; health seeking behaviour and adherence with treatment protocols can be obstructed. The mother-infant relationship can be negatively influenced, leading to poor infant developmental outcomes (i.e., cognitive, emotional and social development) (Goodman et al., 2011; Murray et al., 2011). In addition, couple's relationship seems to be affected, as women with PD have reported increased marital dysfunction in terms of conflictual communication and lack of support, which appeared to persist even after PD relented (Roux et al., 2020). Last but not least, maternal PD has been identified as one of the strongest predictors of paternal PD and it has been estimated that 24%-50% of men whose partners are diagnosed with PD also meet the criteria for minor or major depression (Goodman, 2004).

Recommended treatment options for PD include psychological interventions and pharmacotherapy (Sockol et al., 2013). However, the impact of some medication on the foetus

has not been established as potential associations of antidepressants' use during pregnancy with adverse outcomes on the infant have been reported (Simoncelli et al., 2010). Perinatal individuals have appeared to be reluctant to continue or initiate antidepressant medication stating fears of harming the infant, either in utero or via breast milk (Dennis & Chung-Lee, 2006; Misri et al., 2010; Turner et al., 2008) and preferences for psychotherapy over antidepressant medication when available have been previously reported (Boath & Henshaw, 2001; Ride & Lancsar, 2016). Though, barriers including stigma, poor healthcare experiences (Hadfield & Wittkowski 2017; Megnin-Viggars et al., 2015), and lack of childcare might hinder women's access and compliance to psychological therapies (Goodman, 2009; O'Mahen & Flynn 2008).

Regular perinatal PA is considered a preventive factor for postpartum depressive disorders (ACOG, 2020) while sedentary behaviour has been associated with worse mood, increased risk of depression and somatic symptoms that can interfere with social and daily activities (Poudevigne & O'Connor, 2006). Current international guidelines recommend that pregnant and postpartum women should engage in at least 150min of moderate intensity aerobic PA throughout the week; post-birth activities should be gradually resumed as soon as it is medically safe, taking into consideration the delivery method and the presence of possible complications (WHO, 2020).

Recent meta-analytic evidence suggested that exercise and PA-based interventions were effective in preventing and treating depressive symptoms in pregnant (e.g., Daley et al., 2015) and postpartum women (e.g., McCurdy et al., 2017; Poyatos-León et al., 2017).

However, heterogeneity in PA assessment in RCTs suggests the existence of potential moderators such as intensity, frequency, time point of initiation during pregnancy/postpartum or type of implemented PA (Nakamura et al., 2019). Conclusions about health-related outcomes

originated from potentially unreliable PA measures could lead to misleading recommendations. Systematic assessment of PA with objective measures would improve validity and reliability of research findings and therefore ensure evidence-based recommendations for perinatal populations (Guérin et al., 2018). Moreover, among RCTs which delivered exercise-based interventions, only a small portion of them implemented exercise counselling interventions (Daley et al., 2008; Daley et al., 2015; Forsyth et al., 2017; Huang et al., 2011; Lewis et al., 2014; Mohammadi et al., 2015; Surkan et al., 2012) and only three trials delivered theory-based exercise counselling interventions (Daley et al., 2008; Daley et al., 2015; Lewis et al., 2014) aiming simultaneously at behavioural change. Interventions focusing on exercise behaviour change can increase exercise or reduce sedentariness perinatally (Curie et al., 2013) and while behavioural change techniques (e.g., goal setting, repetition) can provide successful outcomes, the use of theory for developing interventions "directly maps needs and assets to theory-based intervention components and improves generalizability of findings" (Thompson et al., 2017).

The primary aim of this study was to evaluate the effectiveness of an Exercise Counselling (EC) intervention based on the Social Cognitive Theory (Bandura, 1998) and the Transtheoretical Model (TTM) of change (Prochaska & Velicer, 1997) compared to Perinatal Wellbeing Education (PWE) on reducing the depressive symptoms of perinatal individuals recruited via obstetric care practices. Additionally, the effect of the EC intervention on participants' symptoms of anxiety and sleep quality compared to the PWE were assessed. The study's hypothesis was that participants receiving the EC intervention would report lower depressive symptomatology scores at 36weeks gestation and 10weeks post-delivery, as well as lower anxiety levels and less sleeping difficulties compared to the PWE group.

#### **Materials and Methods**

## Trial design, randomization, and data collection

This study was designed as a two-arm randomized controlled trial with participants allocated either to an intervention group receiving the Exercise Counselling (EC) or to an active control group receiving Perinatal Wellbeing Education (PWE). A blocked randomization (using randomly mixed block sizes of two, four and six) was used to allocate participants to the trial arms with a 1:1 ratio. Allocation sequence was concealed from the researcher assigning participants to intervention arms, and sequentially numbered, opaque, sealed envelopes were opened after the enrolled participants completed all pre-intervention outcome measures. This was a single-blinded study. Because of the trial's nature, nor participants or intervention providers could be blinded to the group allocation. Outcome assessors and data analysts were kept blinded to the allocation. All measurement outcomes were recorded at pre-intervention (27weeks gestation), mid-intervention (36weeks gestation) and post-intervention (10weeks post-birth) via individualized, face-to-face meetings (50min-60min) with the researcher at participants' place of accommodation.

## Participants' recruitment

A total of twelve obstetric care practices located in Central and Northwest Greece, were invited to assist with recruitment. Researchers conducted 30-40min informational meetings (face to face or via phone) with the obstetric care providers of five practices that expressed interest about the study. Two obstetric care providers agreed to evaluate which patients were at no known risk that would prevent them from engaging in low to moderate exercise, inform them about the study based on the researchers' instructions and provide them with the study's information sheet. Upon patients' agreement, obstetric care providers forwarded the eligible patients' contact information to the research team. Thereafter, a member of the research team

phoned eligible participants to ensure that inclusion criteria were met, answer any possible questions with respect to the study and arranged the baseline meeting. All patients of both the collaborating practices attended antenatal care at least once a month.

## Eligibility criteria

Patients were considered eligible if they were between 18 and 45 years old, with a singleton gestation from 22 to 26 weeks, in order for the required obstetric examinations for the second trimester to be completed (ultrasound and glucose screening test). Participants were excluded if they had any medical condition that prevented them from safely taking part in low to moderate exercise (LME). Whether participants were nulliparous or multiparous was not a criterion of exclusion. Participants could continue receiving any counselling/behavioural therapies or prescribed medications.

## Intervention group

The intervention group received an Exercise Counselling (EC) intervention aiming to enhance their knowledge, skills, strategies and confidence to participate in regular self-paced exercise. The exercise goal was progressive over time taking into account participant's Stage of Change (SoC) for exercise at pre-intervention, targeting their engagement in at least 150min/week of self-paced exercise. The EC was implemented via eight individualized counselling sessions based on Social Cognitive theory and the theoretical constructs, and the experiential and behavioural processes of the Transtheoretical Model of change (TTM) (Appendix 3). Specifically, participants attended two face-to-face counselling sessions (15-20min) at 27weeks and 36weeks gestation and six phone sessions (5-10min) at 28weeks gestation, 31weeks gestation, 33weeks gestation, 3weeks post-birth, 5weeks post-birth and 8weeks post-birth (Appendix 4).

## Active control group

The active control group received Perinatal Wellbeing Education (PWE) implemented in the same manner as in the intervention group with respect to number and duration of face-to-face and phone sessions by the same researcher. An attempt was made to control for attention and time, in order to determine whether the EC would have a clinical benefit not influenced by the aforementioned factors. The PWE was implemented in eight individualized educational sessions about perinatal mental health, sleep routines, eating habits, accommodation to post birth, social support, networking, time management and self-compassion. Specifically, participants attended two face-to-face counselling sessions (15-20min) at 27weeks and 36weeks gestation and six phone sessions (5-10min) at 28weeks gestation, 31weeks gestation, 33weeksgestation, 3weeks post-birth, 5weeks post-birth and 8weeks post-birth (Appendix 5). Participants of this group received an additional post-intervention face-to-face counselling session (8-10min) on benefits of an active lifestyle at 10weeks post-birth, after the completion of the post-intervention outcome measurements.

#### Measures

*Participants' demographic and background characteristics*: Basic participants' characteristics were collected at baseline. These included age, height, weight, education level, ethnicity, work, marital/family status, parity, and information about prescribed medication, long-term illnesses, smoking habits, and method of conception. During the 3weeks and 5weeks post-birth phone call, information regarding delivery type, delivery complications and method(s) of infant feeding, were collected and relevant participant's characteristics (i.e., smoking habits, prescribed medication) were updated.

*Edinburgh Postnatal Depression Scale (EPDS):* The EPDS is a self-report scale for screening symptoms of depression during pregnancy and postpartum (Cox et al., 1987). It consists of ten items; responses are scored 0, 1, 2, or 3 according to increased severity of each symptom evaluated. Severity range is established as following: none or minimal depression (0–6), mild depression (7–13), moderate depression (14–19), and severe depression (19–30). Positive answer to question ten indicates an immediate risk of self-harm or suicide. The EPDS has been translated in the Greek language and validated in a Greek population (Vivilaki et al., 2009). Recommended effective cut-off scores for screening for probable clinical depression range across countries. However, since no Greek study validated the EPDS against a rigorous clinical interview, in the current study a cut-off score of 13 or greater as recommended by Cox et al. (1987) was adopted.

*Beck Depression Inventory-II (BDI-II):* The BDI-II is a 21-item self-report scale to measure the presence and intensity of depressive symptoms (Beck et al., 1996). Each item is scored on a 4-point Likert scale ranging from 0-3. Scores between 0-13 indicate minimal depression, between 14-19 indicate mild depression, scores from 20 to 28 indicate moderate depression and from 29 to 63 indicate severe depression. The instrument has been validated in the Greek language (Giannakou et al., 2013).

*State-Trait Anxiety Inventory (STAI):* It consists of 20 items assessing trait anxiety and 20 assessing state anxiety (Spielberger, 1983). Items are rated on a 4-point Likert scale with higher scores indicating greater anxiety. The scores for both scales range from 20 to 80 with higher scores reflecting greater levels of anxiety. Interpretation of scores: 20-37, no or low anxiety; 38-44, moderate anxiety; 45-80, high anxiety. The instrument has been validated in the Greek language (Liakos et al., 1984).

*Pittsburgh Sleep Quality Index (PSQI):* The PSQI is a 19-item, self-report measure evaluating the sleep quality of the respondent over the previous month (Buysse et al.,1989). It examines seven components (i.e., subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction), each rated on a 0 to 3 scale. The total score of the seven subscales yields one global score with higher scores indicating greater sleeping difficulties. The instrument has been validated in the Greek language (Kotronoulas et al., 2011).

*Stage of change towards exercise scale (SoC):* The following definition was provided to the respondents: "Regular exercise is every planned in advance physical activity (walking, jogging, aerobic exercise, relaxed run, bicycle, swimming, rowing, etc.) to improve physical fitness. Such activities can be engaged in three up to five times per week, for 20 up to 60 minutes each. The physical activity does not need to be painful to be effective, but it should be done in such level that increases the frequency of breathing and produces sweat." The following question was then asked: "Do you practice often, according to the definition?". Participants responded based on the following five choices: "Yes, I'm doing it for a period more than six months", "Yes, I'm doing it for a period less than six months", "No, but I have the intention to begin within the next 30 days", "No, but I have the intention to begin within the next six months", "No, and I do not have the intention to begin within the next six months" (Bebetsos & Papaioannou, 2012).

*The Athens Physical Activity Questionnaire (APAQ)*: It is a self-report questionnaire that records data on PA of the previous seven days. The questionnaire investigates three classifications: occupational activities, activities at home and recreational activities. The instrument has been validated in the Greek language (Kavouras et al., 2016).

The ActiGraph<sup>TM</sup> GT3X+ accelerometer device: It is a waist worn, small (3.8 cm × 3.7 cm × 1.8 cm), light (27 gr) triaxial accelerometer device (ActiGraph, Pensacola, FL, USA). Participants were instructed to wear it with an elastic belt on the right waist for seven consecutive days during all waking hours except when sleeping and bathing. Data extracted from the accelerometers were considered valid and analysed when worn for  $\geq$  3 days, where a valid day was defined as  $\geq$  8 hours of wear time. The raw acceleration data from each axis were stored in memory and analysed with the ActiGraph<sup>TM</sup> propriety software.

*Social Desirability Scale- Short Form*: It is a 13-item form, used for the assessment of social desirability response tendencies (Reynolds, 1982). It provides information about an individual's response bias and assist in estimating the extent and direction of altered self-presentation that can be taken into account when interpreting assessment results. The instrument has been validated in the Greek language (Lavidas et al., 2019).

## Ethical considerations

A safety protocol was in place for the possibility of worsened depressive symptoms and suicidal ideation for both groups. Thoughts of self-harm and suicidal ideation were assessed at each measurement point using the tenth question of the EPDS and the ninth question of the BDI-II. The study was conducted according to the Helsinki's Declaration (2013) guidelines on ethical standards for research involving human subjects. University Institutional Review Board (IRB) approval was obtained prior to all recruitment activities. The implementation and progress of the study were monitored by the trial's management group via monthly face-to-face meetings. No remuneration was provided to the participants and safety of the collected data was maintained. *Statistical analysis* 

Data are presented as absolute (N) and relative frequencies (%) for the qualitative variables and as median (IQR) for the quantitative variables. In order to compare proportions chi-square test was used. Shapiro-Wilk test was used to test normality distribution for all the quantitative variables. The non-parametric test of Mann-Whitney *U* test was used for the variable comparison between the intervention and the control group. The non-parametric Friedman test, equivalent to repeated measures ANOVA, was used to evaluate changes in every quantitative variable, after the three measurements, among the two groups. Dunn's pairwise post hoc tests were used and finally a Bonferroni correction for multiple testing was applied. Statistical significance was set at p < .05. All analyses were performed using IBM SPSS software (version 24.0). All analyses conducted by intention-to-treat and participants were analysed in the group to which they were allocated.

## Results

A total of 110 women accessed for eligibility between December 2018 and November 2019. Eighty-five women were eligible for inclusion, of which 25 consented to participate and randomised. The flow diagram of the study is illustrated in Figure 1. Participants' demographics and perinatal characteristics are presented in Table 8. No significant between groups differences were found at pre-intervention outcome measures (p> .05) (Table 9). There was a good balance of stages of change (SoC) towards exercise between the study groups at pre-intervention (Table 9). There were no significant between group differences regarding participant's delivery week, delivery mode, breastfeeding routines, weight gain, and post-delivery smoking habits. Attendance rates were 88.55% for the intervention group and 79.79% for the active control group. Overall, participants in this study experienced minimal to mild depressive symptoms, as measured via the primary outcome measure and none of them experienced self-harm or suicidal ideation throughout the study. Participants' scores in STAI -at all three time points- did not indicate anxiety symptoms of clinical significance.

Between and within groups comparisons of primary and secondary outcome measures are demonstrated in Table 10. Overall, symptoms of depression and anxiety in the intervention group improved at mid-intervention and post-intervention compared to the active control group and differences were statistically significant. Sleeping difficulties were lower in the intervention group compared to the active control group, but this difference was significant only at mid-intervention outcome measures (p= .02). Within group comparisons revealed significant reduction in EPDS scores (from pre- to post-intervention, p< .0001) and BDI-II scores (from pre- to post-intervention, p< .0001) among participants in the intervention group (p= .007) while they significantly increased from pre- to mid-intervention and from mid- to post-intervention for participants in the intervention group (p= .007) while they significantly increased from pre- to mid-intervention and from mid- to post-intervention for participants in the active control group (p= .001). Moreover, trait anxiety levels significantly decreased from pre- to mid-intervention for the intervention group (p= .014). Sleep quality significantly improved for both groups from pre- to post-intervention.

There were no significant between or within group differences with respect to participants' total daily exercise as measured via the accelerometer device. However, the active control group implemented significantly more minutes of daily low intensity exercise (LE) at post-intervention compared to the intervention group (p=.05), while participants in the intervention group implemented more minutes of daily moderate intensity exercise (ME) at mid-intervention (p<.0001) and post-intervention (p=.013). The data analysis focused on LE and ME because vigorous exercise (VE) was recorded by less than 10 participants at a very low rate.

Finally, significant between group differences were found in self-reported recreational exercise in favour of the intervention group at mid-intervention (p< .0001) and post-intervention (p= .027). The most commonly reported types of recreational exercise were brisk walking, pram walking, swimming, and cycling.

## Discussion

This study explored the effectiveness of an Exercise Counselling (EC) intervention compared to Perinatal Wellbeing Education (PWE) on alleviating perinatal individuals' depressive symptoms. Symptoms of anxiety and sleep quality were also assessed. The main outcomes of the study are discussed below.

The initial hypothesis of this study was verified, as the EC group participants reported significantly decreased symptoms of depression when compared to the PWE group. Anxiety levels at mid- and post-intervention, as measured with the STAI, were significantly lower when compared to the active control group. Regarding the sleep quality, as measured with the PSQI, the intervention group had significantly less sleeping disturbances compared to the active control group. This difference applied only for the mid- and not for the post-intervention measurements, but this could be explained by the increased responsibilities after the newborn's arrival for the participants of both groups. According to the results, participants of the intervention group engaged in significantly more time of ME at mid- and post-intervention when compared to the active control group. Lastly, the intervention group spent significantly more time on recreational exercise at mid- and post-intervention than the active control group.

This study's results came in line with previous findings regarding the effectiveness of exercise counselling interventions on alleviating depressive symptoms among postpartum individuals (Daley et al., 2015; Lewis et al., 2014). Daley et al. (2015) examined the

effectiveness of a six-month PA counselling intervention based on Theory of Planned Behaviour as a treatment for postnatal depression compared to usual care among postpartum women fulfilling the criteria for major depression. Results demonstrated that significantly more participants in the intervention group were considered "recovered" (46.5% v. 23.8%, p=.03) compared to the group receiving usual care at post-intervention. Lewis et al. (2014) examined the efficacy of a PA counselling intervention for the prevention of postpartum depression. Researchers allocated postpartum participants with a personal or a maternal family history of depression to a six-month theory-based (Social Cognitive Theory & Transtheoretical Model of Change) PA intervention and a wellness/support control condition. The results of their study showed that the PA counselling group reported significantly fewer depressive symptoms than the wellness/support group at post-intervention. No differences in exercise participation between the two study groups were noticed in this study, though exercise components such as intensity or type of PA had not been taken into account (Lewis et al., 2014). Coming to agree with Lewis's findings, this study's participants' total weekly exercise was similar between the study groups at all measurement points. However, significant differences were found in ME between the study groups at mid-intervention and post-intervention. More specifically, participants in the intervention group demonstrated an average of 251.85 min/week and 234.5 min/week of MPA at mid- and post-intervention respectively, while participants in the active control group implemented an average of 81.27 min/week of ME at mid-intervention and an average of 131.39 min/week of MPA at post-intervention. Therefore, our results highlighted intervention's group compliance with the WHO guidelines for pregnant and postpartum women, suggesting that they should participate in at least 150min of moderate physical activity per week (WHO, 2020). Results were also consistent with the meta-analytic evidence by the Davenport et al. study (2018)

which suggested that pregnant individuals should perform at least 644 MET-min/week of moderate to vigorous intensity exercise (e.g., 150 min of moderate intensity exercise) to achieve a moderate effect size in reducing the severity of prenatal depressive symptoms. Moreover, a prospective cohort study examining the association between objectively recorded PA of pregnant women and postpartum depression, found that participants accumulating  $\geq$  150 min/week of moderate to vigorous PA had lower risk of postpartum depression compared to those who did not perform any PA of at least moderate intensity (Shakeel et al., 2018).

With respect to different domains of exercise participation, the results came in line with previous cross-sectional studies suggesting that household/caregiving activities constitute the largest amount of exercise energy expenditure in perinatal populations (Huberty et al., 2016; Nascimento et al., 2015). Participants in the intervention group reported spending less time in household/caregiving exercise at mid- and post-intervention compared to the active control group, yet this difference was not significant. On the contrary, self-reported recreational exercise significantly increased at mid- and post-intervention for the intervention group compared to the PWE group. In addition, although within group comparisons revealed that participants in the intervention group reduced the time spent in recreational exercise at post-intervention compared to mid-intervention, the difference between the study groups remained significant. Previous studies suggested that household activities in comparison to recreational activities, are not usually performed by choice or for pleasure and could result in being stressful or onerous, contributing to women's depressive symptoms (Asztalos et al., 2009; Demissie et al., 2011; White et al., 2017). Another study by van der Waerden et al. (2019) which examined the relationship between domain-specific PA in pregnancy and the occurrence of postpartum depression, found that higher levels of household/caregiving activities in the third trimester were

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associated with increased risk of depressive symptoms at 2-months postpartum. More specifically, authors reported that every additional 30 min/week of moderate-intensity household/caregiving activities would be associated with a 10% increased likelihood of experiencing postpartum depression (Waerden et al., 2019). Simultaneously, research evidence has indicated that engaging in leisure-time PA before or after giving birth can reduce the risk for postpartum depression (Daley et al., 2009; Strom et al., 2009). Suggested potential mediators are alterations in physical self-worth and self-esteem due to succeeding in new tasks, achieving a better sense of personal control, and distracting from negative thoughts or stressful aspects of daily routine (Kull et al., 2012). Occupational PA was excessively reduced at mid- and post-intervention for participants in both study groups as all employed/self-employed participants went under pregnancy and maternity leave during their 3<sup>rd</sup> trimester and first months postpartum. Occupational PA among pregnancy trimesters and postpartum should be further explored with trials including more diverse samples regarding occupational status.

Intervention's group reduction in anxiety symptoms found in this study were not in accordance with recent meta-analytic evidence reporting no association between prenatal exercise and anxiety or the severity of anxiety symptoms in the prenatal or postnatal period (Davenport et al., 2018). Nevertheless, none of the eight RCTs included in this meta-analysis reported objectively measured PA outcomes; only two of them implemented PA counselling components in their interventions (Dodd et al., 2014; Miquelutti et al., 2013), and one of the two recruited solely overweight or obese participants (Dodd et al., 2014). Worth noting is the fact that, apart from the reported significant between-group differences regarding anxiety symptomatology reduction in favour of the EC group, within-group comparisons revealed significant increase in state anxiety in the active control group from pre- to mid-intervention and

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mid- to post-intervention. A plausible explanation for this result could be health and lifestyle or social and relational confounding factors not assessed in this study.

The reported fewer sleeping disturbances for the intervention group at mid-intervention are confirmed by recent meta-analytic findings indicating that exercise of four to sixteen weeks in duration, beginning at the second trimester, can effectively improve sleep quality in pregnant women (Yang et al., 2020). However, authors of this meta-analysis highlighted the high heterogeneity and publication bias of their study. The study by Vladutiu et al. (2014) examined the cross-sectional and longitudinal associations between hours/week of self-reported domain specific and overall MVPA and found no associations at three months postpartum. Overall, the influence of exercise type and intensity on improving perinatal women's sleep quality has not been clarified. Further research is needed to support the effectiveness of exercise on improving sleep quality among perinatal populations.

#### Strengths and limitations

Strengths of this study include the application of the EPDS as the primary outcome measure, as a reliable, well validated, practical and cost-effective tool, excluding the assessment of somatic symptoms (e.g., changes in appetite, energy levels, and sleeping patterns) that are common among perinatal women and therefore could lead to high false-increased scores. Moreover, EPDS is widely used in research, constituting the results comparable with the findings of other, similar studies. An additional strength of this study is the accurate assessment of participants' PA through objective measures, namely accelerometers. Self-report measures of PA, used in the vast majority of trials assessing PA during pregnancy and postpartum, can make the results prone to measurement error and may lead to imprecise and biased estimates (da Silva et al., 2017). In addition, in an attempt to strengthen the validity of the findings, the intervention

and the active control group of this study paralleled one another in terms of contact with researcher and time spent in the research activities, allowing for any differences between the groups to be attributed to the intervention itself, rather than these factors.

This study bears certain limitations. Firstly, the study's sample size is not sufficient enough to ensure the external validity and generalizability of the findings. Recruitment proved more challenging than anticipated and impacted on the sample size. Secondly, an application of a post-trial follow-up design in the study could have contributed significantly to the evaluation of our intervention. Whether this type of interventions could yield long-term benefits has not been investigated.

## Conclusion

Theory-based exercise counselling from the third trimester of pregnancy to the second month post-birth can be effective on alleviating symptoms of depression for perinatal individuals, however, findings of this study should be interpreted taking into account the small sample size. This study's findings suggest that exercise is not automatically related to reduced symptoms of depression and anxiety and that contextual factors associated with exercise parameters and domains (i.e., intensity of PA, domain-specific PA) are probably crucial to such effects. Moreover, in order to enhance perinatal exercise, theory-based interventions could serve as an effective methodological tool for health behaviour change. Results need to be confirmed in large-sized trials including follow-up measurements to profit from precious information for the intervention design in the primary prevention of perinatal depression.

## **CHAPTER VI**

## **RESEARCH PAPER 3**

## WOMEN'S VIEWS AND EXPERIENCES OF A PERINATAL EXERCISE COUNSELLING INTERVENTION: A QUALITATIVE STUDY

## Abstract

Current guidelines support that physical activity during the perinatal period is beneficial for both the mother and the foetus. However, women during their pregnancy and postpartum limit or discontinue their exercise routine. The aim of this study was to illustrate perinatal women's views and experiences deriving from an Exercise Counselling (EC) intervention and evaluate the intervention's acceptability. A qualitative study with semi-structured interviews was conducted with eight adult women of reproductive age recruited from obstetric care practices. Participants had just completed an EC intervention regarding the effectiveness of exercise on perinatal depressive symptoms, implemented in the context of a Randomized Control Trial. The analysis resulted in three overarching themes. Main obstacles to engagement with the EC intervention, which revealed that sociocultural factors had a major impact on women's participation in the intervention; factors that enabled participation in the EC intervention which showed that obstetricians' reinforcement contributed in perinatal women's decision-making process, and that the affective effect of exercise as well as the ability to regulate the intensity pace attributed to the EC intervention adherence; participants' suggestions to improve the EC intervention, which demonstrated that participants would like the partner involvement and engaging to the EC earlier during the pregnancy. Concluding, perinatal behaviour is influenced by various factors such as sociocultural expectations. This is the first qualitative study

evaluating the effect of self-paced intensity of exercise to a perinatal population. Promoting exercise counselling should be a priority in public health policy for women of reproductive age.

## Introduction

Regular PA is typically safe during the perinatal period and is considered beneficial for physical and psychological health. Growing scientific evidence has supported that systematic perinatal PA is considered a preventive factor for postpartum depressive disorders (ACOG, 2020), whereas it has been highlighted that sedentary behaviours may contribute to an increased risk of postpartum depressive symptoms (Nakamura et al., 2019). Maternal and foetal benefits of PA have been associated with improved cardiovascular and muscular health, shorter labour duration and decreased delivery complications, reduced risk for gestational diabetes, hypertension, and preeclampsia (Aune et al, 2014; Perales et al., 2020).

Current guidelines recommend that pregnant women should engage in 20-30min of moderate intensity PA per day, and gradually resume their activities post-birth as soon as it is medically safe, taking into consideration the delivery method and the presence of possible complications (ACOG, 2020). Despite the encouraging scientific proof, part of literature has shown that participation in PA decreases in both frequency and intensity as pregnancy advances (Gaston & Cramp, 2011), particularly during the second and third trimester, and remains low or is completely discontinued for at least three months post-birth (Borodulin et al., 2009). Restrictive factors were lack of time, childcare responsibilities, fatigue, pregnancy-related discomfort, lack of safe and accessible places, and cost of PA (Cramp & Bray, 2011). Further barriers in being physically active include lack of knowledge (Evenson et al., 2009) and family support (Thornton et al., 2006). Indeed, it has been found that exercising activity was more likely to happen when a woman was active pre-pregnancy, had access to safe places and PA was included in her daily routine (e.g., household chores, being active with children) (Weir et al., 2010). Positive influence of social support in perinatal PA behaviours has also been well-

documented (Evenson et al., 2009). An additional preventive factor is that few obstetricians provide PA advice to perinatal women, and when consultation is implemented, is usually perceived as vague (Whitaker et al., 2016), conservative (Evenson & Pompeii, 2010) and outdated or limited (Lindqvist et al., 2018). This was confirmed by qualitative studies exploring regular PA participation experience during pregnancy (Bennet et al., 2013; Currie et al., 2016; Fieril et al., 2014; Hegaard et al., 2010) and perinatally (Findley et al., 2020). These studies pointed out participants' need and desire for comprehensive and concise advice, guidance and support from healthcare professionals and PA facilitators in order to feel safe when being physically active.

Several interventions have been implemented in an attempt to enhance PA engagement among perinatal populations. The interventions mainly aimed at improving specific pregnancy related outcomes such as gestational weight gain (Sagedal et al., 2017), low back pain (Stafne et al., 2012), psychological health (Songøygard et al., 2012), postpartum inactivity (Lewis et al., 2011), post-delivery weight management (Craigie et al., 2011), postpartum well-being (Norman et al., 2010) and clinical conditions (Daley et al., 2015; Reinhardt et al., 2012). In a review and meta-analysis published in 2015 though a positive impact of PA interventions was shown, the majority of the included studies were of high risk of bias for various reasons (e.g., lack of random allocation, high dropout rates, poor PA measurement approaches), thereby safe conclusions could not have been drawn on the effectiveness of the programs (Gilinsky et al., 2015). A more recent review, conducted by Chan et al. (2019), revealed contradictory findings on the impact of PA interventions, yet again the weak methodology of included trials was outlined, therefore the results' inconsistencies could be explained. Furthermore, for both reviews, the included trials examined specific physical and mental outcomes, but did not address the

participants' perception of these interventions. Qualitative methods within trials are widely valued as they can optimise interventions and trial procedures, and facilitate interpretation and transferability of findings in applied practice (Clement et al., 2018). However, research exploring participants' experiences and views on the feasibility and acceptability of the interventions is limited. To the authors' knowledge, in the discipline of perinatal mental health and particularly in perinatal depression, only two qualitative studies have been conducted. They both nested in randomised controlled trials (RCTs) regarding exercise interventions, and explored participants' experiences and views towards acceptability of exercise interventions. Pritchett et al. (2020), who conducted their research with women experiencing postpartum depression, concluded that exercise can be an acceptable, and -in some cases-, preferable treatment for postpartum depression, while Broberg et al. (2020), who conducted their trial with pregnant women with depression or low psychological wellbeing, highlighted the contribution of peer support and increased body awareness in the improvement of participants' psychological health. However, both studies included clinically diagnosed samples and outlined implications of their condition related to either pregnancy or postpartum.

Currently, there are not estimates of the prevalence of perinatal women achieving physical activity guidelines in Greece and studies exploring perinatal women's experience of participating in physical activity and exercise interventions are missing. The aim of the present study was to explore participants' -residence in Central and Northwest Greece- views and experiences deriving from an Exercise Counseling (EC) intervention and evaluate the intervention's acceptability. Further goal for the researchers was to investigate internal and external factors that influence exercise engagement in Greek perinatal population and therefore contribute to the development of applicable and acceptable interventions.

## Materials and methods

## Design

A nested qualitative study, within a RCT of an EC intervention for women during their perinatal period, was conducted. Participants of the two-arm randomized controlled trial allocated either to an intervention group receiving an EC intervention or to an active control group receiving Perinatal Wellbeing Education (PWE). A blocked randomization (using randomly mixed block sizes of two, four and six) was used to allocate participants to the trial arms with a 1:1 ratio. Allocation sequence was concealed from the researcher assigning participants to intervention arms, and sequentially numbered, opaque, sealed envelopes were opened after the enrolled participants completed all pre-intervention outcome measures. This was a single-blinded study. Because of the trial's nature, nor participants or intervention providers could be blinded to the group allocation. Outcome assessors and data analysts were kept blinded to the allocation. RCT's participants attended two face-to-face counselling sessions and six phone sessions from 27weeks gestation to 8weeks post-birth. The EC intervention was based on the Transtheoretical Model of change (TTM) aiming to enhance participants' knowledge, skills, strategies, and confidence to engage in regular self-paced exercise. The active control group received a Perinatal Wellbeing Education (PWE) implemented equally to the EC group with respect to number and duration of counselling sessions. The study was conducted according to the Helsinki's Declaration (2013) guidelines on ethical standards for research involving human subjects. University Institutional Review Board (IRB) approval was obtained prior to all recruitment activities. The implementation and progress of the study were monitored by the trial's management group via monthly face-to-face meetings. No remuneration was provided to the participants and safety of the collected data was maintained. The researcher who delivered

the EC and PWE intervention, the interviews and data analysis is a PhD candidate in the field of perinatal mental health, a licensed psychologist and cognitive behavioural therapist with a professional background in clinical psychology.

## Eligibility criteria

Women were considered eligible for inclusion in the RCT if they were between 18 and 45 years old, with a singleton gestation from 22 to 26 weeks, in order for the required obstetric examinations for the second trimester to be completed (ultrasound and glucose screening test). Participants were excluded if they had any medical condition that prevented them from safely taking part in low to moderate exercise. For moderate-intensity exercise, a person's target heart rate should be 50 -70 % of their maximum heart rate. The maximum rate is based on a person's age. An estimate of a person's maximum heart rate can be calculated as 220 beats per minute (bpm) minus their age. Whether participants were nulliparous or multiparous was not a criterion of exclusion. Participants could continue receiving any counselling/behavioural therapies or prescribed medications. Participants had to have completed the EC intervention (with an attendance rate  $\ge 80\%$ ) in order to be eligible to participate in the qualitative study.

## Participants' recruitment

A total of twelve obstetric care practices located in Central and Northwest Greece, were invited to assist with recruitment. Researchers conducted 30-40min informational meetings (face to face or via phone) with the obstetricians of five practices that expressed interest about the study. Two obstetricians agreed to evaluate which patients were at no known risk that would prevent them from engaging in low to moderate exercise, inform them about the study based on the researchers' instructions and provide them with the study's information sheet. Upon patients' agreement, obstetricians forwarded the eligible patients' contact information to the research team. Thereafter, a member of the research team phoned eligible participants to ensure that inclusion criteria were met, answer any possible questions with respect to the study and arranged the baseline meeting. All patients of both the collaborating practices attended antenatal care at least once a month. All participants in the RCT's intervention group were invited at baseline to take part in an interview after completing the EC intervention and trial's final outcome measurement. Participants were contacted during their eighth week postpartum and offered an interview date that suited their schedule. Involvement was voluntary, confidential and anonymity was reassured.

## Intervention group

The intervention group received an EC intervention aiming to enhance their knowledge, skills, strategies and confidence to participate in regular self-paced exercise. The exercise goal was progressive over time taking into account participants' Stage of Change (SoC) for exercise at pre-intervention, targeting their engagement in at least 150min/week of self-paced exercise. The EC was implemented via eight individualized counselling sessions based on Social Cognitive theory and the theoretical constructs, and the experiential and behavioural processes of the Transtheoretical Model of change (TTM) (Appendix 3). Specifically, participants attended two face-to-face counselling sessions (15-20min) at 27weeks and 36weeks gestation and six phone sessions (5-10min) at 28weeks gestation, 31weeks gestation, 33weeks gestation, 3weeks post-birth, 5weeks post-birth and 8weeks post-birth (Appendix 4).

#### Active control group

The active control group received PWE implemented in the same manner as in the intervention group with respect to number and duration of face-to-face and phone sessions by the same researcher. An attempt was made to control for attention and time, in order to determine

whether the EC would have a clinical benefit not influenced by the aforementioned factors. The PWE was implemented in eight individualized educational sessions about perinatal mental health, sleep routines, eating habits, accommodation to post birth, social support, networking, time management and self-compassion. Specifically, participants attended two face-to-face counselling sessions (15-20min) at 27weeks and 36weeks gestation and six phone sessions (5-10min) at 28weeks gestation, 31weeks gestation, 33weeksgestation, 3weeks post-birth, 5weeks post-birth and 8weeks post-birth (Appendix 5). Participants of this group received an additional post-intervention face-to-face counselling session (8-10min) on benefits of an active lifestyle at 10weeks post-birth, after the completion of the post-intervention outcome measurements.

## Data collection

Basic participants' characteristics were collected at baseline (Table 11). These included age, height, weight, education level, ethnicity, work, marital/family status, parity, and information about prescribed medication, long-term illnesses, smoking habits, and method of conception. During the 3weeks and 5weeks post-birth phone call, information regarding delivery type, delivery complications and method(s) of infant feeding, were collected and relevant participant's characteristics (i.e., smoking habits, prescribed medication) were updated. Participants were asked to complete the Edinburgh Postnatal Depression Scale (EPDS) at pre-intervention (27weeks gestation), mid-intervention (36weeks gestation) and post-intervention (10weeks post-birth) via individualized, face-to-face meetings with the researcher at participants' place of accommodation (Table 12). The EPDS is a self-report scale for screening symptoms of depression during pregnancy and postpartum (Cox et al., 1987). It consists of ten items; responses are scored 0, 1, 2, or 3 according to increased severity of each symptom evaluated.

13), moderate depression (14-19), and severe depression (19-30). Positive answer to question ten indicates an immediate risk of self-harm or suicide. The EPDS has been translated in the Greek language and validated in a Greek population (Vivilaki et al., 2009). Recommended effective cut-off scores for screening for probable clinical depression range across countries. However, since no Greek study validated the EPDS against a rigorous clinical interview, in the current study a cut-off score of 13 or greater as recommended by Cox et al. (1987) was adopted. Moreover, participants were instructed to wear The ActiGraph<sup>TM</sup> GT3X+ accelerometer device with an elastic belt on the right waist for seven consecutive days during all waking hours except when sleeping and bathing at pre-intervention (27weeks gestation), mid-intervention (36weeks gestation) and post-intervention (10weeks post-birth). It is a waist worn, small ( $3.8 \text{ cm} \times 3.7 \text{ cm}$ × 1.8 cm), light (27 gr) triaxial accelerometer device (ActiGraph, Pensacola, FL, USA). Data extracted from the accelerometers were considered valid and analysed when worn for  $\geq 3$  days, where a valid day was defined as  $\geq 8$  hours of wear time. The raw acceleration data from each axis were stored in memory and analysed with the ActiGraph<sup>™</sup> propriety software. An epoch length of 60 seconds was chosen to capture PA. Freedson equation for adults (Freedson et al., 1998) was used to define physical activity cut points and to diagnose time spent in different physical activity intensities (Low PA/ LPA: 100 - 1951 cnts·min-1, Moderate PA/ MPA: 1952 -5724 cnts·min-1). Periods of more than 60 minutes of consecutive zero counts were considered non-wear time (Ward et al., 2005) (Table 12).

Upon completing the EC intervention, audio recorded, semi-structured face to face interviews were conducted in privacy, of approximately 30min length allowing for emerging issues to be explored in a greater depth (Smith & Osborn, 2004). Open-ended questions enabled the researchers to understand and yield meaning to information abstracted (Patton, 2002). An informal conversational approach was adopted, allowing for flexibility, spontaneity, and responsiveness (Patton, 2002). An interview guide (Appendix 6) was developed to ensure main aspects were discussed. Data were anonymised during transcription and stored in accordance with the General Data Protection Regulation (GDPR; 2016). Transcriptions were translated according to the World Health Organization's guidelines following the back-forth procedure for instruments' adaptation.

## Data analysis

A thematic analysis was conducted to develop themes relating to women's views and experiences of participating in the EC intervention (Braun & Clarke, 2006). An inductive approach was used, where transcripts were read and reread numerous times by the researcher (NAT) and initial notes were kept on specific domains relevant to the aim of the study, providing the basis for the development of different themes. Reflective notes were kept for each transcript to moderate the impact of the researcher's own experience upon the analysis (Larkin & Thompson, 2012). Links between the transcripts were made, and clusters of themes reflecting the participants' experiences were created in order to constitute the super-ordinate themes. Finally, credibility checks were conducted and discrepancies regarding the codes and themes were resolved through team discussions.

## **Trustworthiness**

Sensitivity to context was achieved through awareness of relevant literature in the fields of perinatal mental health and exercise, and by considering ethical issues and effective handling of empirical data. Methodological competence in data collection and rigorous reading, analysing and interpreting added depth and latitude in the analysis. Transparency and coherence were ensured through the development of an interview guide and the sharing of coding procedures,
themes and participants' quotes with the research team. Previously achieved familiarization during the EC intervention between the participants and the interviewer contributed to the establishment of good communication and a comfortable environment for sharing (DiCicco Bloom & Crabtree, 2006).

## Results

### Participants' characteristics and themes

A total of 110 women accessed for eligibility between December 2018 and November 2019. Eighty-five women were eligible for inclusion, of which 25 consented to participate and randomised. Out of the 12 potential participants in the intervention group, one had not completed the EC intervention, and three of the remaining 11 participants declined due to time constraints and infant's sickness. Participants' mean age was 33.5 years. Attendance rates were 88.55% for the intervention group and 79.79% for the active control group. Finally, eight interviews were conducted. Women participated in this study during their 10th week post-birth. Participants' characteristics are presented in Table 11. Results are presented according to the three super-ordinate themes (Figure 5); *main obstacles to engagement with the EC intervention; factors that enabled participation in the EC intervention and participants' suggestions to improve the EC intervention*. Verbatim quotes from the interviews are provided to support the themes.

#### Main obstacles to engagement with the EC intervention

Participants discussed the major factors that discouraged their participation in the EC intervention and reflected on their experiences.

The dominant obstacle that emerged and seemed to affect engagement in the EC intervention was reducing or stop being physically active for the sake of being pregnant. Most

participants mentioned there was at least one close relative or friend discouraging them to participate in the EC intervention while being pregnant. For example, one participant mentioned:

My mother in law quoted: "I 'm watching you every evening, wearing your trainers and going for walks, but are you sure all these modern habits are good? Both times I was

pregnant I had to stay in bed throughout. You have to be patient''. (P01, 32years) Another obstacle that most nulliparous participants mentioned was their post-birth forty-day home-stay. The forty-day home-stay is linked to the Christian Orthodox tradition. When forty postpartum days are reached, mother and infant participate in a church ritual where they receive the forty-day blessing from the priest. Before completing forty days both the mother and the child are thought to be particularly vulnerable and, those following the tradition strictly, do not leave the house. Participants acknowledged that staying at home contradicted their needs and wishes, yet they felt bound to conform to the forty-days blessing requirements:

I had a really hard time during my first postpartum month. I was in pain, the baby couldn't sleep and crying all the time, I was crying a lot as well, it wasn't right to leave the house even for a walk until we had reached the forty days postpartum (. . .) there were moments that I was feeling sorry for myself. (P02, 35years)

## Factors that enabled participation in the EC intervention

#### The expert's voice

Advice from obstetricians appeared to be crucial for participants' decision to participate in the EC intervention. Urges and clarifications about perinatal exercise supported participants to engage in the EC when provided by their obstetricians. The need for reassurance that they were not putting the baby at risk with their activities was reported by seven participants. One participant stated: The reassurance from the doctor that as far as I' m not overdoing it, it is beneficial for me and my baby helped me start walking again (. . .) I also noticed that the days following the ultrasounds and the doctor's reassurance that the baby was fine, I tended to be more active. (P03, 31years)

### Positive impact of exercise on moods and wellbeing

Feelings of pleasure, enjoyment and well-being appeared to be among the most compelling factors *that enabled participation in the EC intervention*.

Participants reported a plethora of affective changes both during pregnancy and postpartum. In this study the term "affect" is used as an umbrella term, enclosing core effect, emotions, and moods. A positive affective response was achieved through single or combined factors, including pleasurable sensory/state experiences of exercise, positive attitude towards exercise and expectations of enjoyment. Most participants recalled pleasurable outcomes to the stimulus of exercise during their participation in the EC intervention. Improvements in breathing, sense of activation and stamina as well as a sense of relaxation were commonly experienced. For example, one participant reported:

My breathing was getting better (while walking), I was feeling more energetic and rejuvenated. (P04, 37years)

More than half of the participants were behaviourally engaged to exercise for pleasure and their expectation of enjoyment and calmness strengthened their positive attitude and participation in the EC. For example, one participant stated:

My long walks were such a pleasure (. . .) after a couple of weeks I realized that my most joyful and euphoric moments during that era were while walking and I kept doing it till I gave birth. (P03, 31years)

Six participants reported perceiving exercise as a relief and an effective coping mechanism of unpleasant feelings.

When the baby came, sometimes I was so overwhelmed; I had mood swings all day long. I started finding myself when we started our morning pram-walks (. . .) I am returning home and I feel reset. (P05, 35years)

# Self-paced exercise

Participants' ability to undertake activities throughout the EC intervention in their preferred pace and modified according to their needs, appeared as a strong reinforcement to participate in the intervention.

The type, intensity, and duration of exercise were adjusted multiple times as gestational age increased and the same applied for the postpartum period. Mild discomforts, experienced while being physically active in progressed pregnancy, were perceived as safe and beneficial and participants took complementary actions or adapted their activity's intensity. Four participants highlighted that engaging in self-paced exercise helped them to be in tune with body signals and enhanced their feelings of safety towards the intervention. For example:

Well, there was no pressure, I was in tune with my body, I knew when I had to change my pace. (P01, 32years)

### Participants' suggestions to improve the EC intervention

Participants reflected on their experience of participating in the EC intervention and discussed potential additions and accommodations they thought they would enhance their engagement.

### Partners' involvement

Six participants supported that their partner's involvement in the EC sessions could have been beneficial; if their partners had attended the sessions as well, their awareness towards perinatal exercise benefits could have been enhanced, especially in the mental health domain. One participant reported:

If R. (husband) was in those initial meetings, he would have been more supportive. It took him a while to understand, or to say he understood (laughs), how much it helps me

Moreover, they suggested that their participation could have led them to adopt a more supportive attitude towards their perinatal exercise as a health behaviour in general, with a potential long-lasting positive influence on their lifestyle as a couple. For example:

psychologically, and that it wasn't only for the baby and the labour. (P03, 31years)

There are many things that he (husband) does not understand and it's hard for me to explain. I am not complaining (. . .) he was supportive but if he was in the meetings and had the whole picture, I think he would have tried more and understood better. I mean that maybe I wouldn't have to explain why I need to go for a thirty-minute walk by myself while he is staying with M. (older child) and the baby. (P04, 37years)

## Start earlier

Four participants discussed the potential benefits in case they had been introduced to the EC intervention earlier in their pregnancy.

Maybe if we have started earlier, like in the first trimester, it would have been better. I know, the first trimester is hard for some women, but, for example, I didn't have any problem during my first trimester so I could have started earlier. (P01, 32years)

Only two participants of this study, reported they engaged in regular exercise pre-pregnancy; one of them revealed cutting down her pre-pregnancy physical activities and re-introduced them when she enrolled in the EC intervention:

We should have started earlier! I wouldn't have stopped running (. . .) I don't know, I just thought that exercise was out of the menu and never thought to discuss running with the doctor (. . .) well, I could have dealt better with all this pressure and anxiety during my first trimester If I hadn't quit (running). (P06, 29years)

One participant highlighted the negative impact on her physical and psychological wellbeing the sedentary lifestyle that maintained during the first months of pregnancy:

I hadn't realized that I was so inactive. I spent three months lying down for no reason, I gained weight and I wasn't feeling okey. I think I could have started doing this by the time I found out I was pregnant. (P05, 35years)

Another participant discussed the potential proactive and beneficial role that the PAC intervention might had if initiated pre-pregnancy:

This is my second (child) and I believe that all women planning to get pregnant should have some sort of advice and support to exercise, to be active and not be scared and lay on the couch. We should find ways to help ourselves. (P07, 42years).

# Discussion

The aim of this study was to investigate participants' views and experiences deriving from a EC intervention, explore factors affecting their engagement with the intervention and evaluate the intervention's acceptability. The analysis resulted in three overarching themes: *main obstacles to engagement with the EC intervention, factors that enabled participation in the EC intervention and participants' suggestions to improve the EC intervention.*  Results indicated that participants' engagement with the EC intervention was influenced by sociocultural expectations. Participants' decision to participate in the EC intervention received negative judgment during their pregnancies. Previous studies highlighted that unrequested advice impacted pregnant women's decision towards being physically active (Reichert et al., 2007). Participants in this study did not assert or share their need for being physically active post-birth with their partners or significant others. Though a major change in attitudes towards exercise in pregnancy had initiated since 1985, when the ACOG first approved limited aerobic exercise, this study's participants were challenged by preconceived notions; outdated expectations that pregnant women should stay indoors, avoid any strenuous exertion and reduce unnecessary activity (McCool & Simeone, 2002).

Furthermore, nulliparous participants' compliance with religious traditions highly affected their postnatal engagement with the EC intervention. A similar Mexican ritual ("cuarentena") requires postpartum women to adjust their behaviours regarding physical activity, diet, bathing and housework for a period of at least forty days post-birth (Kieffer et al., 2002). In addition, two Chinese studies, found that physical activity levels were influenced by societal norms, often reinforced by family members, and women felt obliged to comply with their cultural expectations regarding pregnancy (i.e., not lift heavy stuff, not walking too often or too fast) (Evans et al., 2016; Lee et al., 2009). These results were verified by this study, as it showed that social expectations did affect some of the participants' attitude towards the EC intervention engagement. Currently, published literature does not include information about exercise related beliefs and routines associated with religious traditions in Greece and further investigation is needed. Yet, findings of this study highlight the necessity of designing and delivering culturally sensitive interventions to support perinatal women towards handling cultural norms that are not compatible with their needs. Cultural competence among healthcare professionals refers to developing self-awareness, appreciating individual differences, values and patterns and acting flexible (Campinha-Bacote, 2002). The World Health Organization (WHO) emphasised the importance of providing culturally appropriate maternity care as this has been found to improve maternal and newborn health (WHO, 2010). It is also worth noting that the majority of the interventions implemented so far were delivered by healthcare professionals such as nurses or physiotherapists, but not with the entourage of mental health experts (Chan et al, 2019). Involving health professionals with exercise and mental health credentials could assist the identification of sociocultural obstacles when present and facilitate the behavioural alterations towards societal expectations in a notable degree.

The effect of sociocultural factors on participants 'engagement with the EC seemed discouraging, yet obstetricians' role appeared to be crucial in their decision process for exercise engagement; participants valued their obstetricians' reassurance regarding exercise safety during their scheduled visits. Findings of this study were consistent with previous studies; when obstetricians did discuss exercise with their pregnant patients, engagement in exercise was significantly more likely to happen (Aittasalo et al., 2008). This came in line with the existing guidelines about exercise during the perinatal period; these concern obstetricians encouraging their patients to engage in exercise as an important component of optimal health and consultation regarding exercise routines (ACOG, 2020). However, a growing amount of evidence suggests that at least 25% of women are not receiving PA counselling as part of the basic prenatal care (Basu et al., 2014) obtaining limited or confusing information (Ferrari et al., 2013). This finding

was not anticipated in this study, as the sample was purposefully selected and had already participated in an EC intervention upon their obstetrician's consent. However, worth mentioning is the fact that, based on the participants' narratives, discussion on exercise during the perinatal period was initiated by the patients and not the obstetricians. In summary, though women's decisions are influenced by numerous factors, such as their social networks and sociocultural backgrounds (Bennett et al., 2009), obstetricians are a trusted source of information regarding health behaviours and their influence is well-established (McPhail & Schippers, 2012). This said, the co-operation of exercise programs' facilitators with obstetricians could be useful, in order to achieve the maximum utilization of the interventions.

Another major finding that emerged is the positive impact of the EC on participant' moods and wellbeing. This study confirmed previous findings indicating that pregnant women found being physically active to be a great pleasure (Hegaard et al., 2010), and experienced a sense of well-being and satisfaction from training (Duncombe et al., 2009). Participants in this study considered the ability to regulate the intensity of their activities as a crucial component for adherence to the EC, as they felt comfortable, safe, and able to adjust to their body changes in terms of shape and size. Consistent with our findings and with hedonic theory (Ekkekakis & Dafermos, 2012), research in non-perinatal population has shown that when individuals are requested to self-select their exercise intensity, they tend to choose an intensity that leads to a positive affective response (Ekkekakis et al., 2008). Affective response to self-paced exercise seemed to be more positive compared to response to prescribed intensity, even if the self-paced exercise is at higher or comparable levels of intensity of prescribed intensity (Parfitt et al., 2006). Further, self-paced intensity exercise regulated by preferred exertion is linked to lower exertion,

higher intensity and larger improvement in affective states (depression) compared to prescribed intensity exercise among women with depression (Callaghan et al., 2011; Morres et al., 2019).

Moreover, participants clearly pointed out the potential benefit that their partners' involvement in the EC sessions could have. Specifically, they perceived that their partners' participation could have increased the latter's awareness of exercise benefits, potentially leading in a more positive and supportive attitude towards exercise (e.g., take over childcare responsibilities, take initiatives for being physically active as a couple). There is limited research investigating the effectiveness of exercise interventions targeting prospective parents as a dyad. Findings of studies on couple-oriented interventions but different health domains are more effective compared to regular care (Arden Close & McGrath, 2017). In the perinatal mental health field, the critical role of partners' relationships and the interaction between maternal and paternal mental health has led to calls for development of perinatal care facilities that focus on the couple's psychological wellbeing rather than the mother's solely (Davé et al., 2010).

Finally, valuable information emerged with respect to the participants' gestational stage and the EC intervention's initiation. Four participants assumed that their overall health would have been benefited if the intervention had been initiated earlier in the pregnancy. An ideal timepoint for EC during pregnancy and/or postpartum has not been established from research so far. According to the ACOG guidelines, pregnant women are advised to engage in regular exercise after medical clearance, and healthcare providers are advised to encourage their patients to start or maintain a fitness program suitable for their needs and gestational status (ACOG, 2020). Nevertheless, participants' suggestions for an earlier initiation should be interpreted combined with their reports about receiving their obstetric provider's encouragement for exercise participation concurrently with their enrolment in the EC intervention.

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# Limitations of this study

The study bears certain limitations. First, the established familiarity due to the fact that the same researcher conducted the intervention and interviewed the participants could have affected participants' disclosure and make this study prone to social desirability bias. Second, despite the fact that the interviews were conducted immediately upon completion of the intervention, a non-accurate recall on affective response after exercise or a non-full account of cognitive explanations for their decision process could make the study prone to recall bias.

# Conclusion

Promoting exercise and physical activity remains a priority in public health policy for women of childbearing age and the need for obstetricians to counsel patients about exercise has been previously documented. This is the first qualitative study to explore and reveal the importance of self-paced intensity exercise in a perinatal population. In addition, this is the first study to examine and record the potential benefits of EC interventions targeting expectant couples. Findings suggest that developing cultural competence and designing culturally sensitive interventions is fundamental both for obstetricians and researchers. Key issues for future research are to identify effective approaches and strategies to educate obstetricians about perinatal exercise, and to develop relevant protocols that could support the implementation of exercise counselling sessions. Additional research is needed to understand how self-paced exercise is related to acute affective responses to exercise and future exercise behaviour among perinatal population.

### **CHAPTER VII**

## **GENERAL DISCUSSION**

The aim of this research was to: implement a systematic review and meta-analysis in order to synthesize evidence from RCTs investigating the effect of PA and exercise-based interventions on PD symptoms among perinatal individuals recruited via obstetric care practices, conduct a two-arm RCT in order to evaluate the effectiveness of an Exercise Counselling (EC) intervention (from 27weeks gestation to 10weeks post-birth), based on the Transtheoretical Model (TTM) of change, compared to Perinatal Wellbeing Education (PWE), on reducing the depressive symptoms of perinatal individuals recruited via obstetric care practices and implement a qualitative study with semi-structured interviews to explore participants' views and experiences deriving from the Exercise Counselling (EC) intervention and evaluate the intervention's acceptability.

The meta-analytic results suggested that exercise interventions improved PD symptoms in women recruited via perinatal health services. Exercise showed a statistically significant small overall antidepressant effect (SMD = -0.21, 95% CI = -0.32, -0.10, p= 0.0001) with low/non-significant heterogeneity (Q = 17.94, I 2 = 14%, p= 0.30). The RCTs' hypothesis was confirmed. Participants receiving the EC intervention reported lower depressive symptomatology scores at 36weeks gestation and 10weeks post-delivery, as well as lower anxiety levels and less sleeping difficulties compared to the PWE group. Participants' total weekly exercise was similar between the study groups at all measurement points. However, participants in the intervention group demonstrated an average of 251.85 min/week and 234.5 min/week of ME at mid- and post-intervention respectively, while participants in the active control group implemented an average of 81.27 min/week of ME at mid-intervention and an average of 131.39 min/week of ME at post-intervention. Participants in the intervention group reported spending less time in household/caregiving PA at mid- and post-intervention compared to the active control group, while self-reported recreational exercise significantly increased at mid- and post-intervention for the intervention group compared to the PWE group. Findings suggested that exercise is not automatically related to reduced symptoms of depression and anxiety and that contextual factors associated with exercise parameters and domains (i.e., intensity of exercise, domain-specific exercise) seemed to be crucial to such effects. This was further confirmed via the results of the qualitative study that highlighted participants' preference for the self-paced intensity exercise and pointed out that participants' ability to regulate the intensity pace attributed to the EC intervention adherence.

#### Strengths

As described above, this thesis uses a range of research methods to achieve its aim of exploring both the effectiveness and the experience of exercise counselling in alleviating depressive symptoms in perinatal individuals. Different research methodologies are more appropriate to answer different types of research questions. Systematic reviews and meta-analyses have become increasingly important in healthcare settings and help clinicians read them to keep up to date with their field and they are often used as a starting point for developing clinical practice guidelines. Strengths of the meta-analysis is the synthesis of medium to high quality RCT's investigating whether exercise interventions improve PD symptoms in women recruited via perinatal health services excluding studies recruiting community volunteers, and also excluding quasi-RCTs and/or trials with mindful activities (e.g., yoga). Moreover, the heterogeneity levels were low/non-significant suggesting treatment consistency, and the confidence intervals were mainly narrow in contrast to other studies. Another strength is the application of the EPDS as the

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primary outcome measure in the RCT, as a reliable, well validated, practical and cost-effective tool, excluding the assessment of somatic symptoms (e.g., changes in appetite, energy levels, and sleeping patterns) that are common among perinatal women and therefore could lead to high false-increased scores. Moreover, EPDS is widely used in research, constituting the results comparable with the findings of other, similar studies. An additional strength of this study is the accurate assessment of participants' physical exercise through objective measures, namely accelerometers and not self-report measures -used in the vast majority of trials assessing PA during pregnancy and postpartum- that can make the results prone to measurement error and may lead to imprecise and biased estimates (da Silva et al., 2017). In addition, the intervention and the active control group of this study paralleled one another in terms of contact with researcher and time spent in the research activities, allowing for any differences between the groups to be attributed to the intervention itself, rather than these factors. Moreover, another strength is the implementation of a qualitative study to assess the feasibility and acceptability of the intervention. Qualitative methods within trials are widely valued as they can optimise interventions and trial procedures and facilitate interpretation and transferability of findings in applied practice (Clement et al., 2018).

#### Implications for practice

Researchers/clinicians could consider that exercise of an average of 251.85 min/week and 234.5 min/week of ME at mid- (36weeks gestation) and post-intervention (10weeks post-birth) respectively, led to decreased symptoms of depression when compared to the PWE group implementing an average of 81.27 min/week of ME at mid-intervention (36weeks gestation) and an average of 131.39 min/week of ME at post-intervention (10weeks post-birth). Also,

contextual factors associated with exercise parameters and domains (i.e., intensity of exercise, domain-specific exercise) appeared to be crucial to the beneficial effects.

## Limitations

Findings should be interpreted taking into account certain limitations. First, a small number of RCTs included in the meta-analysis, as only 14 RCTs involving perinatal individuals recruited via perinatal health services were available, of which only two RCTs included clinically diagnosed samples. Also, the RCT's sample size was not sufficient enough to ensure the external validity and generalizability of the findings. Recruitment proved more challenging than anticipated and impacted on the sample size.

Future research should focus on clinically diagnosed PD samples and a systematic examination for side effects of perinatal exercise to facilitate firmer conclusions. Also, the application of post-trial follow-up designs is needed in order to assess whether exercise counselling interventions could yield long-term benefits. Finally, additional research is needed to understand how self-paced exercise is related to acute affective responses to exercise and future exercise behaviour among perinatal women.

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#### **APPENDICES**

#### Appendix 1. DSM-V Criteria for Major Depressive Disorder

**A**. Five (or more) of the following symptoms have been present during the same 2-week period and represent a change from previous functioning; at least one of the symptoms is either (1) depressed mood or (2) loss of interest or pleasure.

Note: Do not include symptoms that are clearly attributable to another medical condition.

1. Depressed mood most of the day, nearly every day, as indicated by either subjective report (e.g., feels sad, empty, hopeless) or observation made by others (e.g., appears tearful). (Note: In children and adolescents, can be irritable mood.)

2. Markedly diminished interest or pleasure in all, or almost all, activities most of the day, nearly every day (as indicated by either subjective account or observation).

3. Significant weight loss when not dieting or weight gain (e.g., a change of more than 5% of body weight in a month) or decrease or increase in appetite nearly every day. (Note: In children, consider failure to make expected weight gain.)

4. Insomnia or hypersomnia nearly every day.

5. Psychomotor agitation or retardation nearly every day (observable by others, not merely subjective feelings of restlessness or being slowed down).

6. Fatigue or loss of energy nearly every day.

7. Feelings of worthlessness or excessive or inappropriate guilt (which may be delusional) nearly every day (not merely self-reproach or guilt about being sick).

8. Diminished ability to think or concentrate, or indecisiveness, nearly every day (either by subjective account or as observed by others).

9. Recurrent thoughts of death (not just fear of dying), recurrent suicidal ideation without a specific plan, or a suicide attempt or a specific plan for committing suicide.

**B.** The symptoms cause clinically significant distress or impairment in social, occupational, or other important areas of functioning.

**C.** The episode is not attributable to the physiological effects of a substance or to another medical condition.

Note: Criteria A-C represent a major depressive episode.

Note: Responses to a significant loss (e.g., bereavement, financial ruin, losses from a natural disaster, a serious medical illness or disability) may include the feelings of intense sadness, rumination about the loss, insomnia, poor appetite, and weight loss noted in Criterion A, which may resemble a depressive episode. Although such symptoms may be understandable or considered appropriate to the loss, the presence of a major depressive episode in addition to the normal response to a significant loss should also be carefully considered. This decision inevitably requires the exercise of clinical judgment based on the individual's history and the cultural norms for the expression of distress in the context of loss.

**D**. The occurrence of the major depressive episode is not better explained by schizoaffective disorder, schizophrenia, schizophreniform disorder, delusional disorder, or other specified and unspecified schizophrenia spectrum and other psychotic disorders.

**E**. There has never been a manic episode or a hypomanic episode. Note: This exclusion does not apply if all of the manic-like or hypomanic-like episodes are substance-induced or are attributable to the physiological effects of another medical condition.

DSM-V = Diagnostic and Statistical Manual of Mental Disorders, 5<sup>th</sup> ed.

## Appendix 2. Supporting information for research paper 2.

a) Recruitment and outcome measurement time points with respect to perinatal age.

Trial	Recruitment	Pre-intervention	Mid- intervention	Post-intervention	Follow-up
Daley et al. (2008)	less than 12months postpartum	less than 12months postpartum (52.2weeks)	no	less than 15months postpartum (65.2weeks)	no
Daley et al. (2015)	women received trial information 10-14weeks after birth	within 6months after birth (26.1weeks)	no	within 12months after birth (52.2weeks)	within 18months after birth (78.3weeks)
Forsyth et al. (2017)	6weeks postpartum	6weeks postpartum	no	18weeks postpartum	30weeks postpartum
Haruna et al. (2013)	women who expected to give birth between January and July 2007 voluntarily applied for participation	2months postpartum (8.7weeks)	no	4months postpartum (17.4weeks)	no
Huang et al. (2011-a)	16weeks of pregnancy	16weeks of pregnancy	no	6months postpartum (26.1weeks)	no
Huang et al. (2011-b)	16weeks of pregnancy	24-48hours after birth	no	6months postpartum (26.1weeks)	no
Mohammadi et al. (2015-a)	26-32weeks of pregnancy	26-32weeks of pregnancy	no	1month postpartum (4.35weeks)	2months postpartum (8.7weeks)
Mohammadi et al. (2015-b)	26-32weeks of pregnancy	1month postpartum (4.35weeks)	no	2months postpartum (8.7weeks)	no
Norman et al. (2010)	women ready for discharge from The Angliss Hospital postnatal were invited	6-10weeks postpartum	no	14-18weeks postpartum	18-22weeks postpartum
Perales et al. (2015)	within 12weeks of pregnancy	9-12weeks of pregnancy	no	38-39weeks of pregnancy	no
Robichaud, (2008)	from 6weeks to 12months postpartum	from 6weeks to12 months (52.2weeks) postpartum	no	from 12weeks to 13 and a half months (58.7weeks) postpartum	no
Robledo-Colonia et al. (2012)	not specified	16-20weeks of pregnancy	no	28-32weeks of pregnancy	no
Shelton, (2015)	4-6weeks postpartum	4-6weeks postpartum	no	10-12weeks postpartum	no
Surkan et al. (2012)	6-20weeks postpartum	6-20weeks postpartum (on average, participants' infants aged 1.8 months at enrolment)	no	15months postpartum (65.2weeks)	no
Vargas-Terrones et al. (2019)	<16weeks of pregnancy	12-16weeks of pregnancy	no	38-39weeks of pregnancy	6weeks postpartum
Yang & Chen, (2018)	not specified	6weeks postpartum	10weeks postpartum	18weeks postpartum	no

b) E-databases

Scopus, PubMed, PsycINFO, SPORT Discus, Science Citation Index and Conference

Proceedings (Web of Science), The Cochrane Library (Cochrane Database of Systematic

Reviews), Cochrane Central Register of Controlled Trials, the World Health Organization

(WHO) International Clinical Trials Registry Platform (ICTRP), the ProQuest Dissertations &

Theses (PQDT).

Key words/ MEdical Subject Heading (MESH) terms.

Exercise, physical activity, pregnancy, postpartum, postnatal, perinatal, depression, mental

health.

c) Search Strategy for PubMed and Scopus

Database: PubMed

exercise	"exercise" [MeSH Terms] OR "exercise" [All Fields]
physical activity	"exercise" [MeSH Terms] OR "exercise" [All Fields] OR ("physical" [All
	Fields]) OR "physical activity" [All Fields]
pregnant	"gravidity"[MeSH Terms] OR "gravidity"[All Fields] OR "pregnant"
	[All Fields]
postpartum	"postpartum period"[MeSH Terms] OR ("postpartum"[All Fields] AND
	"period"[All Fields]) OR "postpartum period"[All Fields] OR "
	postpartum"[All Fields]
depression	"depressive disorder" [MeSH Terms] OR ("depressive" [All Fields] AND
	"disorder"[All Fields]) OR "depressive disorder"[All Fields] OR
	"depression"[All Fields] OR "depression"[MeSH terms]
Humans [Mesh]	"humans"[MeSH Terms]

#### Results= 446

Database: Scopus

KEY (exercise) OR TITLE-ABS-KEY (physical AND activity) AND TITLE-ABS-KEY (pregnant) OR TITLE-ABS-KEY (postnatal) OR TITLE-ABS-KEY (mothers) AND TITLE-ABS-KEY (depression)) AND DOCTYPE (ar OR re) AND PUBYEAR > 1997 AND (LIMIT-TO (LANGUAGE, "English"))

Results = 359

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# **Appendix 3. Processes of change according to the Transtheoretical Model of Change**

# (TTM).

Process	Short description
Ex	speriential processes
Consciousness raising	Increase awareness towards benefits of an active lifestyle and risks of a sedentary lifestyle.
Dramatic relief	Express feelings about engaging in exercise and being sedentary.
Self re-evaluation	Cognitive and affective assessment of one's self-image towards adopting an active or inactive lifestyle.
Environmental re-evaluation	Assessment of how exercise and sedentary routines affect one's environment.
Self-liberation	Enhance belief that change is possible and take responsibility for own actions. Choice and commitment to achieve desirable changes.
Be	havioural processes
Social liberation	Social support towards exercise behaviours.
Stimulus control	Avoid or countering stimuli that elicit being sedentary or hinder exercise.
Counter-conditioning	Replace sedentary behaviours with exercise behaviours.
Reinforcement/contingency management	Reward for accomplishing changes and reaching exercise goals while attenuate reinforcement for sedentary behaviours.
Helping relationships	Build or enhance a supportive network for exercise behaviours.

Appendix	4.	Exercise	Counselling	(EC) agenda.
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Time point/type of communication	Exercise Counselling (EC)
27weeks gestation/face-to-face meeting	Discuss benefits/considerations of exercise during pregnancy and risks of inactivity. Elaborate on myths and misconceptions. Enhance future exercise engagement.
28weeks gestation/phone call	Discuss long-term goals and set short-term goals taking into account participant's stage of behaviour change (according to the TTM).
31weeks gestation/phone call	Discuss obstacles/facilitators to accomplish exercise goal, initiate decisional balance. Discuss problem solving strategies (when needed).
33weeks gestation/phone	Assist with exercise goal setting & daily exercise routine plan. Enhance motivation and self-efficacy for exercise.
36weeks gestation/face-to-face meeting	Receive feedback from participants' engagement in exercise. Explore or develop reward system. Discuss problem-solving strategies (when needed). Summary of exercise accomplishments and reinforcement.
3weeks post-birth/phone call	Discuss post-birth lifestyle adoption challenges and complications related to exercise. Discuss benefits/considerations of postpartum exercise depending on participant's needs and conditions.
5weeks post-birth/phone call	Assess post-birth exercise goals and plans. Discuss challenges. Assist with development/enhancement of supportive network for exercise.
8weeks post-birth/phone call	Discuss commitment strategies to exercise. Promote maintenance of an active lifestyle.

TTM = Transtheoretical Model of Change

Appendix	5.	Perinatal	Wellh	being	Education	(PWE)	agenda.
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Time point/type of communication	Perinatal Wellbeing Education (PWE)
27weeks gestation/face-to-face meeting	Information on perinatal mental health challenges.
28weeks gestation/phone call	Information on healthy sleep routines.
31weeks gestation/phone call	Information on healthy eating routines.
33weeks gestation/phone call	Information on social networking.
36weeks gestation/face-to-face meeting	Information on potential post-birth lifestyle adoption challenges.
3weeks post-birth/phone call	Information on time-management and personal time-out.
5weeks post-birth/phone call	Information on self-compassion.
8weeks post-birth/phone call	Information on social support.

#### Appendix 6. Interview guide questions.

How did you feel about being physically active/exercising during your perinatal period?

Can you describe if you felt any difference in your body when you were exercising? Did you feel different right after or days after?

Can you describe if and how exercising affected you emotionally?

Were there any effects on your wellbeing (negative/ positive)? Can you elaborate?

In what sense (if any) did exercising affected your daily live (e.g., family, work, recreational activities)?

Were there any difficulties/obstacles you dealt with/had to overcome in order to exercise? How did they affect you?

Based on your experience, which factors encouraged/discouraged you from participating in exercise?

Which part/element of the exercise counselling intervention worked best for you?

What do you think that could have been done better? Any additions or changes you think that would have been helpful? In what way?

## **Appendix 7. Scales and Questionnaires.**

Beck Depression Inventory BDI-II

## ΕΡΩΤΗΜΑΤΟΛΟΓΙΟ ΣΥΝΑΙΣΘΗΜΑΤΟΣ

Παρακαλούμε να επιλέξετε την απάντηση που εκφράζει καλύτερα πως αισθάνεστε τον τελευταίο μήνα. Σημειώστε μία απάντηση από κάθε ενότητα.

- Α. 0. Δεν αισθάνομαι λυπημένη.
  - 1. Αισθάνομαι λυπημένη ή μελαγχολική.
  - 2α. Είμαι λυπημένη ή μελαγχολική συνεχώς και δεν μπορώ να απαλλαγώ από αυτό.
  - 2β. Είμαι τόσο μελαγχολική ή δυστυχισμένη ώστε αυτό μου προξενεί πόνο.
  - 3. Είμαι τόσο μελαγχολική ή δυστυχισμένη ώστε δεν μπορώ να το αντέξω.
- B. Δεν είμαι ιδιαίτερα απαισιόδοξη ή αποθαρρυνμένη για το μέλλον.
  - 1. Αισθάνομαι χωρίς θάρρος για το μέλλον.
  - 2α. Μου φαίνεται ότι δεν έχω τίποτα καλό να περιμένω από το μέλλον
  - 2β. Μου φαίνεται ότι δεν θα ξεπεράσω τις δυσκολίες μου.
  - Μου φαίνεται ότι το μέλλον είναι χωρίς ελπίδα και ότι τα πράγματα δεν μπορεί να φτιάξουν.
- Γ. 0. Δεν αισθάνομαι αποτυχημένη.
  - 1. Μου φαίνεται ότι είμαι αποτυχημένη περισσότερο από τους άλλους ανθρώπους
  - 2α. Αισθάνομαι ότι έχω πετύχει στη ζωή μου πολύ λίγα πράγματα άξια λόγου.
  - 2β. Καθώς σκέφτομαι τη ζωή μου μέχρι τώρα το μόνο που βλέπω είναι πολλές αποτυχίες
  - 3. Αισθάνομαι ότι είμαι τελείως αποτυχημένο σαν άτομο (σύζυγος μητέρα).
- Δ. 0. Δεν αισθάνομαι ιδιαίτερα δυσαρεστημένη.
  - 1α. Αισθάνομαι βαριεστημένη σχεδόν όλη την ώρα.
  - 1β. Δεν απολαμβάνω τα πράγματα όπως πρώτα.
  - 2. Δεν με ευχαριστεί πια τίποτα.
  - 3. Αισθάνομαι δυσαρεστημένη με το κάθε τι
- Ε. 0. Δεν αισθάνομαι ιδιαίτερα ένοχο τον εαυτό μου.
  - 1. Πολλές φορές αισθάνομαι κακή ή χωρίς αξία.
  - 2α. Αισθάνομαι πολύ ένοχη.
  - 2β. Τον τελευταίο καιρό αισθάνομαι κακή ή χωρίς αξία σχεδόν όλη την ώρα.
  - 2. Αισθάνομαι ότι είμαι πολύ κακή ή ανάξια.

- Ζ. 0. Δεν αισθάνομαι ότι τιμωρούμαι.
  - 1. Αισθάνομαι ότι κάτι κακό μπορεί να μου συμβεί.
  - 2. Αισθάνομαι ότι τιμωρούμαι ή ότι θα τιμωρηθώ.
  - 3α. Αισθάνομαι ότι μου αξίζει να τιμωρηθώ.
  - 3β. Θέλω να τιμωρηθώ
- Η. 0. Δεν αισθάνομαι απογοητευμένη από τον εαυτό μου
  - 1α Αισθάνομαι απογοητευμένη από τον εαυτό μου.
  - 1β. Δεν μου αρέσει ο εαυτός μου.
  - 2. Σιχαίνομαι τον εαυτό μου.
  - 3. Μισώ τον εαυτό μου.
- Θ. 0. Δεν αισθάνομαι ότι είμαι χειρότερη από τους άλλους.
  - 1. Είμαι αυστηρή με τον εαυτό μου για τις αδυναμίες μου.
  - 2α. Κατηγορώ τον εαυτό μου για τα λάθη μου.
  - 2β. Κατηγορώ τον εαυτό μου για κάθε κακό που συμβαίνει.
- I. 0. Δεν μου έρχονται σκέψεις να κάνω κακό στον εαυτό μου.
  - Μου έρχονται σκέψεις να κάνω κακό στον εαυτό μου αλλά ποτέ δεν θα έκανα κάτι τέτοιο.
  - 2α. Μου φαίνεται ότι θα ήταν καλύτερα να πέθαινα.
  - 2β. Μου φαίνεται ότι η οικογένειά μου θα ήταν καλύτερα αν πέθαινα.
  - 2γ. Έχω συγκεκριμένα σχέδια αυτοκτονίας.
  - 2. Θα αυτοκτονούσα αν μπορούσα.
- Κ. 0. Δεν κλαίω περισσότερο από το συνηθισμένο.
  - 1. Κλαίω τώρα περισσότερο από ότι συνήθως.
  - 2. Κλαίω συνεχώς δεν μπορώ να το σταματήσω
  - 3. Άλλοτε μπορούσα να κλάψω, αλλά τώρα μου είναι αδύνατο να κλάψω αν το θέλω.
- Λ. 0. Δεν είμαι περισσότερο εκνευρισμένη από ότι συνήθως.
  - 1. ενοχλούμαι ή εκνευρίζομαι περισσότερο από ότι συνήθως.
  - 2. Αισθάνομαι διαρκώς εκνευρισμένη.
  - 3. Δεν εκνευρίζομαι τώρα για πράγματα που με νευριάζανε συνήθως.
- Μ. 0. Δεν έχω χάσει το ενδιαφέρον μου για άλλους ανθρώπους.
  - Ενδιαφέρομαι τώρα λιγότερο για τους άλλους ανθρώπους από ότι παλιότερα.
  - 2. Έχω χάσει το περισσότερο ενδιαφέρον μου για τους άλλους ανθρώπους και τα αισθήματά μου για αυτούς έχουν λιγοστέψει.
  - Έχω χάσει όλο το ενδιαφέρον μου για τους άλλους ανθρώπους και δεν νοιάζομαι καθόλου για αυτούς.
- Ν. 0. Είμαι το ίδιο αποφασιστική όπως πάντα.
  - 1. Τελευταία αναβάλλω το να παίρνω αποφάσεις.
  - 2. Έχω μεγάλη δυσκολία στο να παίρνω αποφάσεις.

- 3. Δεν μπορώ να πάρω καμιά απόφαση.
- Ξ. 0. Δεν μου φαίνεται ότι η εμφάνισή μου είναι χειρότερη από άλλοτε.
  - 1. Ανησυχώ μήπως μοιάζω γερασμένη και αντιπαθητική.
  - 2. Αισθάνομαι ότι έγινε τέτοια αλλαγή επάνω μου, ώστε να φαίνομαι αντιπαθητική.
  - 3. Μου φαίνεται ότι είμαι άσχημη και αποκρουστική.
- Ο. Ο. Τα καταφέρνω στη δουλειά μου όπως και πρώτα.
  - 1α. Χρειάζεται να κάνω ιδιαίτερη προσπάθεια για να αρχίσω κάποια δουλειά.
  - 1β. Δεν τα καταφέρνω στη δουλειά μου όπως πρώτα.
  - 2. Χρειάζεται να πιέσω πολύ τον εαυτό μου για να κάνω κάτι.
  - 3. Μου είναι αδύνατο να εργαστώ.
- Π. 0. Κοιμάμαι τόσο καλά όσο συνήθως.
  - 1. Ξυπνώ το πρωί πιο κουρασμένη από άλλοτε.
  - 2. Ξυπνώ το πρωί 2 3 ώρες νωρίτερα από άλλοτε και δυσκολεύομαι να ξανακοιμηθώ.
  - 3. Ξυπνώ νωρίς κάθε μέρα και δεν μπορώ να κοιμηθώ πάνω από 5 ώρες το 24ωρο.
- P. 0. Δεν κουράζομαι ευκολότερα από ότι συνήθως.
  - 1. Κουράζομαι τώρα ευκολότερα από πρώτα.
  - 2. Κουράζομαι με το παραμικρό που κάνω.
  - 3. Κουράζομαι τόσο εύκολα ώστε δεν μπορώ να κάνω τίποτε.
- Σ. 0. Η όρεξή μου δεν είναι χειρότερη από άλλοτε.
  - 1. Η όρεξή μου δεν είναι τόσο καλή όσο άλλοτε.
  - 2. Η όρεξή μου είναι πολύ χειρότερη τώρα.
  - 3. Δεν έχω πια καθόλου όρεξη.
- Τ. 0. Δεν έχω χάσει σχεδόν καθόλου βάρος τον τελευταίο καιρό.
  - 1. Έχω χάσει περισσότερο από 2 κιλά.
  - 2. Έχω χάσει περισσότερο από 4 κιλά.
  - 3. Έχω χάσει περισσότερο από 7 κιλά.
- Υ. 0. Δεν με απασχολεί η υγεία μου περισσότερο από άλλοτε.
  - 1. Με απασχολούν πόνοι ή βαρυστομαχιά ή δυσκοιλιότητα.
  - Με απασχολεί τόσο πολύ το πως αισθάνομαι ή το τί αισθάνομαι ώστε μου είναι δύσκολο να σκεφτώ τίποτε άλλο.
  - 3. Είμαι εντελώς απορροφημένη με το τι αισθάνομαι.
- Φ. 0. Δεν έχω προσέξει τελευταία καμιά αλλαγή στο ενδιαφέρον μου για το σεξ.
  - 1. Ενδιαφέρομαι τώρα λιγότερο για το σεξ από ότι συνήθως.
  - 2. Ενδιαφέρομαι πολύ λιγότερο τώρα για το σεξ.
  - 3. Έχω χάσει τελείως το ενδιαφέρον μου για το σεξ.

## ΕΡΩΤΗΜΑΤΟΛΟΓΙΟ ΓΙΑ ΤΗΝ ΠΕΡΙΓΕΝΝΗΤΙΚΗ ΚΑΤΑΘΛΙΨΗ (EPDS)

Είστε έγκυος ή έχετε γεννήσει πρόσφατα; Θα θέλαμε να μάθουμε πως αισθάνεστε. Παρακαλώ τσεκάρετε την απάντηση που περιγράφει καλύτερα πως αισθάνεστε τις ΤΕΛΕΥΤΑΙΕΣ 7 ΜΕΡΕΣ, όχι το πώς αισθάνεστε σήμερα μόνο.

## 1. Μπορούσα να γελώ και να βλέπω την ευχάριστη πλευρά των πραγμάτων

🗆 Όπως πριν 🛛 Λιγότερο από πριν 🗖 Πολύ λιγότερο από πριν 🖄 Καθόλου

## 2. Περίμενα με χαρά να συμβούν πράγματα

🗆 Όπως πριν 🛛 Λιγότερο από πριν 🗆 Πολύ λιγότερο από πριν 🗆 Καθόλου

## 3. Κατηγορούσα τον εαυτό μου χωρίς αιτία, όταν κάτι πήγαινε στραβά

□ Ναι, τις περισσότερες φορές □ Ναι, μερικές φορές □ Όχι τόσο συχνά □ Όχι, καθόλου

## 4. Ήμουν αγχωμένη ή στενοχωρημένη χωρίς σοβαρό λόγο

🗆 Όχι, καθόλου 🛛 🗆 Πολύ σπάνια 🔅 Ναι, μερικές φορές 🖓 Ναι, πολύ συχνά

## 5. Φοβόμουν και πανικοβαλλόμουν χωρίς ιδιαίτερο λόγο

🗆 Ναι, αρκετά συχνά 🛛 Ναι, μερικές φορές 🖓 Όχι τόσο συχνά 🖓 Όχι, καθόλου

#### 6. Πνιγόμουν από τις καταστάσεις

□ Ναι, τις περισσότερες φορές □ Ναι, μερικές φορές □ Όχι τόσο συχνά □ Όχι, καθόλου

#### 7. Ήμουν τόσο λυπημένη, που είχα δυσκολία να κοιμηθώ

□ Ναι, τις περισσότερες φορές
□ Ναι, μερικές φορές
□ Όχι τόσο συχνά
□ Όχι, καθόλου

#### 8. Ένιωθα στενοχωρημένη ή μίζερη

```
□ Ναι, τις περισσότερες φορές
□ Ναι, αρκετά συχνά
□ Όχι τόσο συχνά
□ Όχι, καθόλου
```

#### 9. Ήμουν τόσο λυπημένη που έκλαιγα

□ Ναι, τις περισσότερες φορές
□ Ναι, αρκετά συχνά
□ Μόνο περιστασιακά
□ Όχι, καθόλου

## 10. Είχε περάσει από την σκέψη μου να κάνω κακό στον εαυτό μου

🗆 Ναι, αρκετά συχνά 🛛 Μερικές φορές 🗆 Σχεδόν ποτέ 🗆 Ποτέ

## State Trait Anxiety Inventory STAI

## $EP\Omega THMATO \Lambda O\Gamma IO \ A\Gamma XOY\Sigma \ TOY \ SPIELBERGER$

ΟΔΗΓΙΕΣ: Παρακάτω υπάρχουν φράσεις που οι άνθρωποι συνηθίζουν να χρησιμοποιούν για να περιγράψουν τον εαυτό τους. Διαβάστε κάθε φράση και μετά βάλτε σε κύκλο τον αντίστοιχο αριθμό στα δεξιά της φράσης για να δείξετε πώς αισθάνεστε τώρα, δηλαδή αυτή τη στιγμή. Δεν υπάρχουν σωστές ή λανθασμένες απαντήσεις. Μην ξοδεύετε πολλή ώρα για κάθε μία φράση, αλλά δώστε την απάντηση που φαίνεται να ταιριάζει πιο καλά <u>σ' αυτό που αισθάνεστε τώρα</u>.

	Καθόλου	Λίγο	Μέτρια	Πολύ
1. Αισθάνομαι ήρεμη	1	2	3	4
2. Αισθάνομαι ασφαλής	1	2	3	4
3. Νιώθω μια εσωτερική ένταση	1	2	3	4
4. Αισθάνομαι σφιγγμένος	1	2	3	4
5. Αισθάνομαι άνετα	1	2	3	4
6. Αισθάνομαι αναστατωμένη	1	2	3	4
7. Ανησυχώ αυτή τη στιγμή για ενδεχόμενες ατυχίες	1	2	3	4
8. Αισθάνομαι ικανοποιημένη	1	2	3	4
9. Αισθάνομαι φοβισμένη	1	2	3	4
10. Αισθάνομαι βολικά	1	2	3	4
11. Αισθάνομαι αυτοπεποίθηση	1	2	3	4
12. Αισθάνομαι νευρικότητα	1	2	3	4
13. Τρέμω από νευρικότητα	1	2	3	4
14. Είμαι αναποφάσιστη	1	2	3	4
15. Είμαι χαλαρωμένη	1	2	3	4
16. Αισθάνομαι ευχαριστημένη	1	2	3	4
17. Ανησυχώ	1	2	3	4
18. Είμαι μπερδεμένη	1	2	3	4
19. Αισθάνομαι σταθερότητα	1	2	3	4
20. Αισθάνομαι ευχάριστα	1	2	3	4

ΟΔΗΓΙΕΣ: Παρακάτω υπάρχουν φράσεις που οι άνθρωποι συνηθίζουν να χρησιμοποιούν για να περιγράψουν τον εαυτό τους. Διαβάστε κάθε φράση και μετά βάλτε σε κύκλο τον αντίστοιχο αριθμό στα δεξιά της φράσης για να δείξετε πώς αισθάνεστε συνήθως. Δεν υπάρχουν σωστές ή λανθασμένες απαντήσεις. Μην ξοδεύετε πολλή ώρα για κάθε μία φράση, αλλά δώστε την απάντηση που φαίνεται να ταιριάζει πιο καλά <u>σ' αυτό που αισθάνεστε γενικά</u>.

	Καθόλου	Λίγο	Μέτρια	Πολύ
21. Αισθάνομαι ευχάριστα	1	2	3	4
22. Αισθάνομαι νευρική και ανήσυχη	1	2	3	4
23. Είμαι ικανοποιημένη με τον εαυτό μου	1	2	3	4
24. Εύχομαι να μπορούσα να είμαι τόσο ευτυχισμένη όσο οι άλλοι φαίνονται να είναι	1	2	3	4
25. Αισθάνομαι αποτυχημένη	1	2	3	4
26. Αισθάνομαι αναπαυμένη	1	2	3	4
27. Είμαι ήρεμη, ψύχραιμη και συγκεντρωμένη	1	2	3	4
28. Αισθάνομαι πως οι δυσκολίες συσσωρεύονται ώστε να μην μπορώ να τις ξεπεράσω	1	2	3	4
29. Ανησυχώ υπερβολικά πολύ για κάτι που στην ποαγματικότητα δεν έχει σημασία	1	2	3	4
30. Είμαι χαρούμενη	1	2	3	4
31. Κάνω δυσάρεστες σκέψεις	1	2	3	4
32. Μου λείπει η αυτοπεποίθηση	1	2	3	4
33. Αισθάνομαι ασφαλής	1	2	3	4
34. Παίρνω εύκολα αποφάσεις	1	2	3	4
35. Αισθάνομαι ανεπαρκής	1	2	3	4
36. Είμαι ικανοποιημένη	1	2	3	4
37. Κάποια ασήμαντη σκέψη μου περνά από το μυαλό και μ' ενοχλεί	1	2	3	4
38. Παίρνω τις απογοητεύσεις τόσο πολύ στα σοβαρά ώστε δεν μπορώ να τις διώξω από τη σκέψη μου	1	2	3	4
39. Είμαι ένας σταθερός χαρακτήρας	1	2	3	4
40. Έρχομαι σε μια κατάσταση έντασης ή αναστάτωσης όταν σκέφτομαι τις τρέχουσες ασχολίες και τα ενδιαφέροντά μου	1	2	3	4

Stage of change SoC

## Ορισμός συστηματικής σωματικής δραστηριότητας

#### Ασκείστε συχνά, σύμφωνα με τον ορισμό;

«Τακτική άσκηση είναι κάθε προσχεδιασμένη φυσική δραστηριότητα (π.χ. γρήγορο περπάτημα, αεροβική άσκηση, χαλαρό τρέζιμο, ποδήλατο, κολύμπι, κωπηλασία, κλπ.) που γίνεται για να βελτιώσει τη φυσική κατάσταση. Αυτού του είδους οι δραστηριότητες μπορεί να εκτελεστούν 3 έως 5 φορές την εβδομάδα για 20 έως 60 λεπτά κάθε φορά. Η άσκηση δεν χρειάζεται να είναι επώδυνη για να είναι αποτελεσματική, αλλά πρέπει να γίνεται έτσι ώστε να αυζάνει το ρυθμό της αναπνοής σας».

Διαβάστε πρώτα **όλες** τις παρακάτω **απαντήσεις** και μετά σημειώστε με Χ **μόνο μία**, η οποία σας αντιπροσωπεύει.

 Όχι, δεν είμαι συστηματικά σωματικά δραστήρια, και δεν σκοπεύω να γίνω στους επόμενους 6 μήνες.

Οχι, δεν είμαι συστηματικά σωματικά δραστήρια, αλλά σκοπεύω να γίνω στους επόμενους 6 μήνες.

Όχι, δεν είμαι συστηματικά σωματικά δραστήρια, αλλά σκοπεύω να γίνω στις επόμενες 30 ημέρες.

□ Ναι, είμαι συστηματικά σωματικά δραστήρια, αλλά για λιγότερο από έξι μήνες.

Ναι, είμαι συστηματικά σωματικά δραστήρια για περισσότερο από έξι μήνες.

# Athens Physical Activity Questionnaire APAQ

Παρακαλούμε σκεφτείτε <u>τις τελευταίες 7 μέρες (εβδομάδα)</u>. Θα θέλαμε να μας δώσετε κάποιες πληροφορίες για την φυσική σας δραστηριότητα

Φυσική Δραστηριότητα στην Εργασία

<ul> <li>Ποια είναι η βασική σ</li> <li>Εργαστήκατε τις τελει</li> <li>Όχι →προ</li> </ul>	τας απασχόληση; υταίες 7 μέρες; οχωρήστε στην ενότητα :	2			
Ναι Πόσ	ες μέρες; (1)				
– Πόσες ώρες τη μ – Εκ των οποίων π	ιέρα κατά μέσο όρο; όσο χρόνο κατά μέσο ό	άρες/ ηι φο καταναλώσ	μέρα εργα τατε:	σίας(2)	
			'Ωρες,	/ ημέρα εργασίας	]
	καθιστή				(3)
	όρθια				(4)
	σε κίνηση				(5)
	μεταφέροντας βάρος				(6)
	Συνολικός χρόνος εργα	ασίας			
Πόσος χρόνος χρειάστηκ	κε για τη μετακίνηση σας	από και προς	τη δουλειά	α σας αυτές τις μέρες	;
			)	νεπτά/ ημέρα (7)	
Εκ του οποίου χρ	<b>ρόνου</b> πόση ώρα	α)περπατήσα	ата;	λεπτά/ ημέρα (8)	
		β)οδηγήσατε	;	λεπτά/ ημέρα (9)	

# Φυσική Δραστηριότητα στο Σπίτι

Κατά τη διάρκεια των τελευταίων 7 ημερών πόσες ώρες (κατά μέσο όρο) <b>την <u>ημέρα</u>:</b>
-κοιμηθήκατε (συμπεριλαμβανομένου και τυχόν μεσημεριανού ὑπνου);ώρες/ ημέρα (10)
-είδατε τηλεόραση-βίντεο; ώρες/ ημέρα (11)
Κατά τη διάρκεια των τελευταίων 7 ημερών πόσες ώρες <u>συνολικά </u> καταναλώσατε:
-για ελαφριές δουλειές σπιτιού (π.χ. μαγείρεμα, πλύσιμο πιάτων κλπ);ώρες/ εβδομάδα (12)
-για βαριές δουλειές σπιτιού(π.χ. πλύσιμο στο χέρι, σφουγγάρισμα κλπ);ώρες/ εβδομάδα(13)
-για διάβασμα και στον υπολογιστή (εκτός ωρών εργασίας); ώρες/ εβδομάδα (14)

Φυσική Δραστηριότητα για Ψυχαγωγία

	Ώρες/εβδομάδα	
χορέψατε σε club ή/και bar:		(15)
ήσασταν καθιστή ή στεκόσασταν όρθια με φίλους σε		(16)
καφετέρια – μπαρ – ταβέρνα – εστιατόριο- θέατρο-σινεμά;		
περπατήσατε για ψυχαγωγία (βόλτα στα μαγαζιά, στο		(17)
πάρκο κλπ) και για μετακίνηση (εκτός μετακίνησης προς και		
από τη δουλειά):		
Nai Öxi		
	Zułose:	
Ναι ΄Οχι ναι τι ακριβώς κάνετε και πόσες ώρες <b>συνολικά</b> τις τελευταίες	7 μἑρες: Ώρες/εβδομ	ιάδα
Ναι Όχι ναι τι ακριβώς κάνετε και πόσες ώρες <b>συνολικά</b> τις τελευταίες	7 μέρες: Ώρες/εβδομ	ιάδα (18)
Ναι Όχι ναι τι ακριβώς κάνετε και πόσες ώρες <b>συνολικά</b> τις τελευταίες	7 μέρες: Ώρες/εβδομ	ιάδα (18) (19)
Ναι ΄Οχι ναι τι ακριβώς κάνετε και πόσες ώρες <b>συνολικά</b> τις τελευταίες	7 μέρες: Ώρες/εβδομ	ιάδα (18) (19) (20)
Ναι Οχι ναι τι ακριβώς κάνετε και πόσες ώρες <b>συνολικά</b> τις τελευταίες	7 μέρες: Ώρες/εβδομ βδομάδα (σημειώστε	iάδα (18) (19) (20) <b>μόνο ένα</b> );
Ναι Οχι ναι τι ακριβώς κάνετε και πόσες ώρες <b>συνολικά</b> τις τελευταίες Μοτοσικλέτα Ι.Χ. Περ	7 μέρες: Ώρες/εβδομ εβδομάδα (σημειώστε οπατώντας	ιάδα (18) (19) (20) <b>μόνο ένα</b> ); Ποδήλατο

Pittsburg Sleep Quality Index PSQI

# ΕΛΛΗΝΙΚΟΣ ΔΕΙΚΤΗΣ ΠΟΙΟΤΗΤΑΣ ΥΠΝΟΥ ΤΟΥ PITTSBURGH (GR-PSQI)

ΟΔΗΓΙΕΣ:

Οι ακόλουθες ερωτήσεις σχετίζονται με τις συνήθειες ύπνου σας κατά τη διάρκεια των τελευταίων τριάντα (30) ημερών μόνο.

Οι απαντήσεις σας θα πρέπει να είναι όσο το δυνατόν ακριβέστερες για την πλειοψηφία των ημερών και νυχτών κατά την περίοδο των τελευταίων τριάντα (**30**) ημερών. Παρακαλούμε απαντήστε σε όλες τις ερωτήσεις.

1. Κατά τη διάρκεια των τελευταίων τριάντα (30) ημερών, τι ώρα πηγαίνατε συνήθως για ύπνο το βράδυ;

ΣΥΝΗΘΗΣ ΩΡΑ ΥΠΝΟΥ \_\_\_\_\_

2. Κατά τη διάρκεια των τελευταίων τριάντα (30) ημερών, πόσο χρόνο (σε λεπτά) σας έπαιρνε για να αποκοιμηθείτε κάθε βράδυ;

## ΑΡΙΘΜΟΣ ΛΕΠΤΩΝ

3. Κατά τη διάρκεια των τελευταίων τριάντα (30) ημερών, τι ώρα σηκωνόσασταν συνήθως το πρωί;

## ΣΥΝΗΘΗΣ ΩΡΑ ΕΓΕΡΣΗΣ

4. Κατά τη διάρκεια των τελευταίων τριάντα (30) ημερών, πόσες ώρε<u>ς κοιμόσασταν</u> <u>πραγματικά</u> τη νύχτα; (Αυτό μπορεί να είναι διαφορετικό από τον αριθμό των ωρών που ξοδέψατε στο κρεβάτι)

ΩΡΕΣ ΠΡΑΓΜΑΤΙΚΟΥ ΥΠΝΟΥ ΑΝΑ ΝΥΧΤΑ \_\_\_\_\_
Για κάθε μία από τις επόμενες ερωτήσεις, σημειώστε τη μία καλύτερη απάντηση. Παρακαλούμε απαντήστε σε όλες τις ερωτήσεις.

5. Κατά τη διάρκεια των τελευταίων τριάντα (30) ημερών, πόσο συχνά είχατε πρόβλημα να κοιμηθείτε, εξαιτίας του ότι	Όχι κατά τις τελευταίες 30 ημέρες	Λιγότερο από μία φορά τη βδομάδα	Μία ή δύο φορές τη βδομάδα	Τρεις ή περισσότερες φορές τη βδομάδα
α. Δεν μπορούσατε να κοιμηθείτε μέσα σε 30 λεπτά;	0	1	2	3
β. Ξυπνούσατε στη μέση της νύχτας ή νωρίς το πρωί;	0	1	2	3
γ. Χρειαζόταν να σηκωθείτε για να χρησιμοποιήσετε την τουαλέτα;	0	1	2	3
δ. Δεν μπορούσατε να αναπνεύσετε άνετα;	0	1	2	3
ε. Βήχατε ή ροχαλίζατε δυνατά;	0	1	2	3
στ. Αισθανόσασταν υπερβολικό κρύο;	0	1	2	3
ζ. Αισθανόσασταν υπερβολική ζέστη;	0	1	2	3
η. Βλέπατε άσχημα όνειρα;	0	1	2	3
θ. Πονούσατε;	0	1	2	3
ι. Άλλος λόγος (ή άλλοι λόγοι). Παρακαλούμε περιγράψτε:	0	1	2	3

6. Κατά τη διάρκεια των τελευταίων τριάντα (30) ημερών, πόσο συχνά πήρατε φάρμακα (με συνταγή ή χωρίς συνταγή γιατρού) για να σας βοηθήσουν να κοιμηθείτε;	0	1	2	3
7. Κατά τη διάρκεια των τελευταίων τριάντα (30) ημερών, πόσο συχνά είχατε πρόβλημα να παραμείνετε ξύπνια ενώ οδηγούσατε, τρώγατε ή συμμετείχατε σε μία κοινωνική δρα- στηριότητα;	Όχι κατά τις τελευταίες 30 ημέρες	Λιγότερο από μία φορά τη βδομάδα	Μία ή δύο φορές τη βδομάδα	Τρεις ή περισσότερες φορές τη βδομάδα
<ol> <li>Κατά τη διάρκεια των</li> <li>τελευταίων τριάντα (30)</li> <li>ημερών, κατά πόσο ήταν</li> <li>πρόβλημα για εσάς να</li> <li>διατηρήσετε αρκετό</li> </ol>	Καθόλου πρόβλημα	Μόνο ένα μικρό πρόβλημα	Αρκετό πρόβλημα	Πολύ μεγάλο πρόβλημα
ενθουσιασμό για να κάνετε πράγματα και να ολοκληρώσετε δραστηριότητες;	0	1	2	3

	Πολύ καλή	Μάλλον καλή	Μάλλον κακή	Πολύ κακή
9. Κατά τη διάρκεια των				
τελευταίων τριάντα (30)				
ημερών,πώς θα				
βαθμολογούσατε την	0	1	2	3
ποιότητα του ύπνου σα				
γενικώς;				

Social Desirability Form

Οδηγίες: Παρακαλούμε διαβάστε τις παρακάτω προτάσεις και υποδείξτε εάν η πρόταση αληθεύει για σας

προσωπικά (NAI) ή δεν αληθεύει (OXI). Βάλτε σε κύκλο την απάντηση που διαλέγετε.

<ol> <li>Μερικές φορές το βρίσκω δύσκολο να καταβάλλω μεγάλη προσπάθεια στην εργασία μου εάν δεν έχω υποστήριξη από τα κοντινά μου πρόσωπα.</li> </ol>	NAI	OXI
2. Κάποιες φορές αισθάνομαι πικραμένος/η όταν δεν πετυχαίνω τους στόχους μου.	NAI	OXI
<ol> <li>Υπήρξαν φορές που εγκατέλειψα αυτό που έκανα επειδή πίστευα ότι δεν ήμουν αρκετά ικανός/ή.</li> </ol>	NAI	OXI
4. Υπήρξαν φορές που ήθελα να επαναστατήσω σε ανωτέρους μου αν και ήξερα ότι είχαν δίκιο.	NAI	OXI
5. Άσχετα με το ποιόν συνομιλώ, είμαι πάντα πολύ καλός ακροατής/τρια.	NAI	OXI
6. Υπήρξαν στιγμές που εκμεταλλεύτηκα κάποιον.	NAI	OXI
7. Είμαι πάντα πρόθυμος/η να το παραδεχτώ όταν κάνω λάθος.	NAI	OXI
<ol> <li>Κάποιες φορές προσπαθώ να ανταποδώσω με το ίδιο τρόπο παρά να συγχωρέσω και να ξεχάσω.</li> </ol>	NAI	OXI
9. Είμαι πάντοτε ευγενικός/ή με τους άλλους, ακόμη και με άτομα που διαφωνούν μαζί μου.	NAI	OXI
10. Ποτέ δεν έχω ενοχληθεί όταν άτομα εξέφρασαν ιδέες πολύ διαφορετικές από τις δικές μου.	NAI	OXI
11. Υπήρξαν στιγμές που ζήλεψα πολύ την καλή τύχη των άλλων.	NAI	OXI
12. Κάποιες φορές ενοχλούμαι αφάνταστα από άτομα που μου ζητούν χάρες.	NAI	OXI
13. Ποτέ δεν έχω πει κάτι επίτηδες που να πληγώσει κάποιον άλλο.	NAI	OXI

## Έντυπο συναίνεσης σε έρευνα

## Τίτλος Έρευνας: Η φυσική δραστηριότητα κατά τη διάρκεια της περιγεννητικής περιόδου.

**Σκοπός της έρευνας:** Η σύγκριση της προώθησης της φυσικής δραστηριότητας με την συνήθη περιγεννητική φροντίδα στη βελτίωση της ψυχικής υγείας των γυναικών κατά τη περιγεννητική περίοδο.

Διαδικασία: Οι συμμετέχουσες θα κληθούν να συμμετάσχουν σε έξι συμβουλευτικές συναντήσεις, διάρκειας 10 λεπτών. Τρείς συναντήσεις θα πραγματοποιηθούν δια ζώσης σε χρόνο και τόπο βολικό για τις συμμετέχουσες και τρείς συναντήσεις μέσω τηλεφώνου. Στις συμμετέχουσες θα χορηγηθεί αξελερόμετρο, το οποίο θα τους ζητηθεί να χρησιμοποιήσουν 3 φορές κατά τη διάρκεια της συμμετοχής τους, με την καθοδήγηση της ερευνήτριας. Επίσης, θα ζητηθεί στις συμμετέχουσες να συμπληρώσουν ερωτηματολόγια αξιολόγησης ψυχολογικών δεικτών συνολικά 3 φορές κατά τη διάρκεια της συμμετοχής τους.

**Ασφάλεια:** Δεν υπάρχει κανένας αναμενόμενος κίνδυνος από τη συμμετοχή στη μελέτη αυτή. Η συμβουλευτική παρέμβαση έχει σχεδιαστεί σύμφωνα με τις οδηγίες του Αμερικανικού Κολεγίου Μαιευτήρων και Γυναικολόγων, έχει εγκριθεί από την Επιτροπή Δεοντολογίας του Πανεπιστημίου Θεσσαλίας (3/10/2018, Protocol Number.:1408) και θα υλοποιηθεί με τη σύμφωνη γνώμη του γυναικολόγου της συμμετέχουσας.

Δημοσίευση αποτελεσμάτων: Η συμμετοχή σας στην έρευνα συνεπάγεται ότι συμφωνείτε με την μελλοντική δημοσίευση των αποτελεσμάτων της, με την προϋπόθεση ότι οι πληροφορίες θα είναι ανώνυμες και δε θα αποκαλυφθούν τα ονόματα των συμμετεχόντων. Τα δεδομένα που θα συγκεντρωθούν θα κωδικοποιηθούν με αριθμό, ώστε το όνομα σας δε θα φαίνεται πουθενά.

Πληροφορίες: Μη διστάσετε να κάνετε ερωτήσεις γύρω από το σκοπό ή την διαδικασία της έρευνας. Αν έχετε οποιαδήποτε αμφιβολία ή ερώτηση ζητήστε μας να σας δώσουμε διευκρινίσεις. Ελευθερία συναίνεσης: Η συμμετοχή σας στην έρευνα είναι εθελοντική. Είστε ελεύθερη να μην συναινέσετε ή να διακόψετε τη συμμετοχή σας όποτε το επιθυμείτε και δεδομένα που ενδεχομένως έχετε συνεισφέρει θα καταστραφούν.

**Δήλωση συναίνεσης:** Διάβασα το έντυπο αυτό, κατανοώ τις διαδικασίες που θα ακολουθήσω και συναινώ να συμμετάσχω.

Στοιχεία Επικοινωνίας Ερευνητών:...

Ημερομηνία: \_\_/ \_\_/ \_\_.

Ονοματεπώνυμο και υπογραφή συμμετέχουσας Υπογραφή ερευνητή