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Effects and processes of physical activity interventions during pregnancy

A PhD project based on the FitMum randomised controlled trial

PhD thesis

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Principal supervisor: Bente Merete Stallknecht

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Effects and processes of physical activity interventions during pregnancy
- a PhD project based on the FitMum randomised controlled trial

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Signe de Place Knudsen, Askov, April 2022

Papers comprised in this PhD thesis

This PhD thesis represents the completion of my enrolment at the Graduate School of Health and Medical Sciences, University of Copenhagen from January 2018 to April 2022, including one year of maternity leave.

The thesis is based on the following three manuscripts:

Paper 1

Caroline Borup Roland*, **Signe de Place Knudsen***, Saud Abdulaziz Alomairah*, Anne Dsane Andersen, Jane M. Bendix, Tine D. Clausen, Stig Molsted, Andreas Kryger Jensen, Grete Teilmann, Astrid Pernille Jespersen, Jakob Eg Larsen, Gerrit van Hall, Emil Andersen, Romain Barrès, Ole Hartvig Mortensen, Helle Terkildsen Maindal, Lise Tarnow, Ellen Christine Leth Løkkegaard, Bente Stallknecht. (2021). Structured supervised exercise training or motivational counselling during pregnancy on physical activity level and health of mother and offspring: FitMum study protocol. BMJ Open, 11, e043671. http://dx.doi.org/10.1136/bmjopen-2020-043671

*Contributed equally. This paper is also included in the PhD theses of Caroline Borup Roland and will be in the PhD thesis of Saud Abdulaziz Alomairah.

Paper 2

Signe de Place Knudsen*, Saud Abdulaziz Alomairah*, Caroline Borup Roland, Anne Dsane Jessen, Ida-Marie Hergel, Tine D. Clausen, Jakob Eg Larsen, Gerrit van Hall, Andreas Kryger Jensen, Stig Molsted, Jane M. Bendix, Ellen Løkkegaard, Bente Stallknecht. Effects of structured supervised exercise training versus motivational counselling on physical activity in pregnant women: FitMum - a randomised controlled trial. *In review in the Journal of Medical Internet Research.*

*Contributed equally. This paper will also be included in the PhD thesis of Saud Abdulaziz Alomairah.

Paper 3

Signe de Place Knudsen, Saud A. Alomairah, Caroline Borup Roland, Anne Dsane Andersen, Stig Molsted, Tine D. Clausen, Ellen Løkkegaard, Jane M. Bendix, Julie Bønnelycke, Bente Stallknecht, Helle Terkildsen Maindal. Physical activity during pregnancy: a mixed methods process evaluation of the FitMum randomised controlled trial interventions. *Attached as a manuscript.*

During my PhD enrolment, I have as a co-author contributed to other manuscripts of which the following are published:

Freja Holmberg Krøner, **Signe de Place Knudsen**, Caroline Borup Roland, Saud Abdulaziz Alomairah, Stig Molsted. Validity and reliability of the Danish version of the pregnancy physical activity questionnaire to assess levels of physical activity during pregnancy. Journal of Maternal-Fetal and Neonatal Medicine, 2020

Emma Bendix, Freja Holmberg Krøner, **Signe de Place Knudsen**, Jane M. Bendix, Stig Molsted. Cross-cultural adaption, translation and reliability tests of the Danish version of the Pregnancy Exercise Self-Efficacy Scale. Sexual and Reproductive Healthcare, 2020

English summary

Physical activity during pregnancy is widely recognised as a beneficial and safe lifestyle component among healthy women with uncomplicated pregnancies. Danish and international recommendations prescribe moderate-intensity physical activity for 210 and 150 minutes per week, respectively, throughout pregnancy for all pregnant women with uncomplicated pregnancies. Nevertheless, the high prevalence of inadequate physical activity during pregnancy (as well as in general) is a global health challenge. Therefore, the effectiveness of different physical activity intervention strategies should be compared to clarify how pregnant women can most effectively increase their physical activity levels and improve health of themselves and their offspring.

The focus of this PhD is effectiveness and processes of interventions on physical activity during pregnancy to support the understanding of implementing physical activity in pregnant women's everyday lives. The main objective of the PhD thesis was to investigate the effects of offering two different physical activity interventions to healthy inactive pregnant women on physical activity level and to explore the implementation and mechanisms of impact. The three-arm randomised controlled trial, FitMum, forms the basis of the thesis and the three papers; a description of the two physical activity interventions (Paper 1), an interpretation of the effects of the physical activity interventions on physical activity level (Paper 2), and a process evaluation of the physical activity interventions in a mixed methods design (Paper 3).

The FitMum study was conducted from 2018 to 2021. Overall, 219 pregnant women were randomised to one of three groups; structured supervised exercise training (EXE) offered three times per week throughout pregnancy (n=87), motivational counselling on physical activity (MOT) offered in four individual and three group counselling sessions during pregnancy (n=87), or a control group (CON) receiving standard care (n=45) (Paper 1).

In Paper 2, the effects of the two physical activity interventions on moderate-to-vigorous intensity physical activity and complimentary physical activity outcomes were investigated and compared to standard care. Physical activity was continuously measured throughout pregnancy by a commercial wrist-worn activity tracker. Overall, it was found that pregnant women who were offered EXE were more physically active at moderate-to-vigorous intensity than those who were offered CON. No differences in moderate-to-vigorous intensity physical activity were found between EXE and MOT nor between pregnant women who were offered MOT or CON. However, participants who were offered MOT perceived themselves physically active at a higher intensity than participants who were offered EXE. Further, moderate-to-vigorous intensity physical activity was maintained at the same

level throughout pregnancy in all three groups. Moderate-to-vigorous intensity physical activity was positively associated with the number of exercise sessions attended in EXE, yet participants attended in half of the recommended sessions. Attendance increased with the onset of COVID-19 and the unintended alteration of the interventions into online setups. However, participants did not increase their physical activity. EXE and MOT contained several interacting components. This complexity will underlie the entire thesis.

Paper 3 contains a mixed methods process evaluation of the two physical activity interventions in the FitMum study. The Medical Research Council framework for process evaluations were applied and it was revealed that participants enrolled in FitMum were educated and had high everyday life autonomy. The interventions were well delivered with high fidelity in physical and online interventions. The low attendance rate in EXE might be explained by the fact that participation was more feasible for participants with high everyday life flexibility even though the intervention accessibility was high. Participants in EXE and MOT had opposing views of physical activity. Participants who were offered EXE primarily perceived themselves physically active when they attended an exercise session with a certain level of intensity. In contrast, participants who were offered MOT recognised daily activities, including those with lower intensity, as sufficient activity. Participants who were offered MOT perceived themselves more vigorously active than what was objectively measured, which might be caused by the intense physical activity attention during intervention.

In conclusion, findings from this PhD thesis and the papers show that it is possible for pregnant women to increase their physical activity level when they are offered EXE. However, the intervention is intense and challenging to adhere to. Due to the complexity, it does not appear that one single strategy or component is sufficient for pregnant women to implement the recommended physical activity into their everyday life. Based on the most effective intervention in the FitMum study (EXE), a combination of physical attendance and frequent home-based, online exercise sessions might increase the attendance rate and the physical activity among pregnant women in a future perspective.

Dansk resume

Alle gravide kvinder med ukomplicerede graviditeter anbefales af danske og internationale myndigheder at være fysisk aktive ved moderat intensitet i henholdsvis 210 og 150 minutter om ugen under hele graviditeten. Ikke desto mindre udgør et lavt fysisk aktivitetsniveau under graviditet (og generelt) en global sundhedsudfordring. Derfor bør effektiviteten af forskellige interventionsstrategier for fysisk aktivitet undersøges for at klarlægge, hvordan gravide kvinder mest effektivt kan øge deres fysiske aktivitetsniveau og forbedre sundheden.

Denne ph.d.-afhandling fokuserer på interventioner, der adresserer fysisk aktivitet i graviditeten. Afhandlingen omhandler både interventionernes effekt, og processuelle forhold, der kan forklare en mulig effekt, samt bidrage med viden om forhold, der har betydning for eventuelt fremtidig implementering. Der er fokus på hvem, interventionerne når, hvordan de virker, og om de virker. Hovedformålet med ph.d.-afhandlingen var at undersøge effekter af to forskellige fysisk aktivitetsinterventioner til raske, inaktive gravide kvinder ved at måle på kvindernes fysiske aktivitetsniveau. Derudover var målet at undersøge implementering og virkningsmekanismer bag effekterne. Et tre-armet randomiseret kontrolleret forsøg, FitMum, danner grundlag for afhandlingen og de tre artikler; en beskrivelse af to komplekse fysiske aktivitetsinterventioner (Artikel 1), en undersøgelse af interventioners effekt på det fysiske aktivitetsniveau (Artikel 2) og en procesevaluering af interventionerne i et mixed methods design (Artikel 3).

FitMum blev gennemført fra 2018 til 2021. Samlet set blev 219 gravide kvinder randomiseret til én af tre grupper; struktureret superviseret holdtræning, der blev tilbudt tre gange om ugen under hele graviditeten (n=87), motiverende vejledning om fysisk aktivitet, der blev tilbudt i fire individuelle og tre gruppesessioner i løbet af graviditeten (n=87), eller en kontrolgruppe, der modtog standard svangreomsorg (n=45) (Artikel 1).

I Artikel 2 blev effekterne af de to interventioner på fysisk aktivitet ved moderat til høj intensitet samt supplerende fysiske aktivitetseffekter undersøgt og sammenlignet med standard svangreomsorg. Fysisk aktivitet blev løbende målt under hele graviditeten ved hjælp af en kommerciel håndledsbåret aktivitetsmåler. Kvinderne, der blev tilbudt holdtræning, var mere fysisk aktive ved moderat til høj intensitet end de kvinder, der blev tilbudt standard svangreomsorg. Der blev ikke fundet nogen forskelle i fysisk aktivitet ved moderat til høj intensitet mellem de to interventionsgrupper eller mellem de kvinder, der fik tilbudt motiverende vejledning eller standard svangreomsorg. Deltagerne, der fik tilbudt motiverende vejledning, opfattede dog sig selv som mere fysisk aktive ved høj intensitet end deltagerne, der fik tilbudt holdtræning. Deltagerne i alle tre grupper opretholdt det

samme niveau af fysisk aktivitet ved moderat til høj intensitet under hele graviditeten. Fysisk aktivitet ved moderat til høj intensitet var positivt associeret med antallet af holdtræningssessioner, men deltagelsesgraden var mindre end halvdelen af den anbefalede. Deltagelsen blandt kvinderne i holdtræningsgruppen steg, da interventionerne blev tilbudt online pga. COVID-19 restriktioner. Deltagerne i holdtræningsgruppen øgede dog ikke deres fysiske aktivitetsniveau. De to interventioner bestod af flere interagerende komponenter. Denne kompleksitet vil være underliggende for hele afhandlingen.

Artikel 3 indeholder en procesevaluering af de to fysisk aktivitetsinterventioner. Et rammeværk af The Medical Research Council blev anvendt og ved at benytte både kvantitative og kvalitative metoder fandt vi, at deltagerne i FitMum var højtuddannede og havde en høj autonomi i forhold til deres egen hverdagsliv. Interventionerne blev leveret som forventet og med høj fidelitet i både de fysiske og online interventioner. Holdtræningsinterventionen var lettest at tilgå for deltagere med høj fleksibilitet i deres hverdag, selv om holdtræningen blev tilbudt seks dage om ugen. Deltagerne, der fik tilbudt motiverende vejledning, vurderede sig selv som mere fysisk aktive ved høj intensitet i forhold til det, der blev målt objektivt. Det kan skyldes den intense opmærksomhed på fysisk aktivitet under interventionen. Deltagerne i EXE og MOT havde modsatrettede opfattelser af fysisk aktivitet. Deltagere, der fik tilbudt EXE, opfattede sig primært som fysisk aktive, når de deltog i en træningssession med en vis intensitet. I modsætning hertil anerkendte deltagere, der blev tilbudt MOT, daglige aktiviteter, herunder aktiviteter med lavere intensitet, som tilstrækkelig aktivitet. Deltagere, der fik tilbudt MOT, opfattede sig selv som mere fysisk aktive ved høj intensitet i forhold til det, der objektivt blev målt. Det kan skyldes den intense opmærksomhed på fysisk aktivitet under interventionen.

Alt i alt viser resultaterne af denne ph.d.-afhandling og tilhørende artikler, at gravide kvinder kan blive mere fysisk aktive, når de tilbydes struktureret superviseret holdtræning. Interventionen er dog intensiv og udfordrende at indgå i. På grund af kompleksiteten, ser det ikke ud til, at en enkelt strategi eller komponent er tilstrækkelig til, at gravide kvinder kan implementere den anbefalede mængde og intensitet af fysisk aktivitet i deres hverdag. På baggrund af den mest effektive intervention i FitMum (struktureret superviseret holdtræning) kan en kombination af fysisk fremmøde og hyppige hjemmebaserede online-træningssessioner dog øge fremmødegraden og det fysiske aktivitetsniveau blandt gravide kvinder i et fremtidigt perspektiv.

Abbreviations

ACOG	The American College of Obstetricians and Gynaecologists
CI	Confidence interval
CON	Control group
DLW	Doubly labelled water
EXE	Structured supervised exercise training
GA	Gestational age
MET	Metabolic equivalent of task
Min	Minutes
MOT	Motivational counselling on physical activity
MVPA	Moderate-to-vigorous-intensity physical activity
PA	Physical activity
PPAQ	Pregnancy Physical Activity Questionnaire
RCT	Randomised controlled trial
SD	Standard deviation

Introduction

Pregnancy is a unique period of a woman's life in which lifestyle behaviours, including physical activity (PA) behaviours, can significantly improve the health of the pregnant woman as well as their offspring[1–3]. The World Health Organisation recommends that in the absence of contraindications, all pregnant women should be physically active throughout pregnancy for least 150 minutes (min) per week at moderate intensity[1]. In Denmark, the Health Authorities recommend pregnant women to achieve at least 30 min of PA at moderate intensity per day corresponding to 210 min per week[4]. These recommendations apply both for women who were physically inactive before becoming pregnant and those already active when entering the pregnancy[1,4]. In addition, the American College of Obstetricians and Gynaecologists (ACOG) advise that women who habitually engaged in vigorous intensity PA before pregnancy can continue to do so during pregnancy[2]. Physical inactivity is described as one of the most significant global health risks[5–7]. Despite substantial evidence, PA during pregnancy has been surrounded by myths, dos, and don'ts for years. Resistance towards PA and lack of knowledge on how to perform PA still exist[8].

The present PhD thesis focuses on interventions addressing PA during pregnancy as it is important to understand the mechanisms underlying pregnant women's health behaviour and how PA interventions can support a physically active pregnancy. The overall aim is to explore how healthy, inactive pregnant women can increase their PA. The thesis is based on the randomised controlled trial (RCT), FitMum: Fitness for good health of mother and child. The thesis takes a mixed methods perspective to explore the mechanisms driving PA behaviour in pregnancy by integrating quantitative results from the RCT and qualitative exploratory findings from interviews. The thesis is based on three papers, covering

- a description of the three-arm randomised controlled trial FitMum, which includes two physical activity interventions (Paper 1),
- the effects of the physical activity interventions on physical activity level during pregnancy (Paper 2),
- and a process evaluation of reach, fidelity, dose, and mechanisms of impact of the physical activity interventions during pregnancy (Paper 3)

Table 1 shows a brief overview of the three papers, including data collection, methods, and results.

	Paper 1	**Paper 2**	**Paper 3**
Title	Structured supervised exercise training or motivational counselling during pregnancy on PA level and health of mother and offspring: FitMum study protocol	Effects of structured supervised exercise training or motivational counselling on pregnant women's PA level: FitMum - a randomized controlled trial	PA during pregnancy: a mixed methods process evaluation of the FitMum randomised controlled trial interventions
Objective	To describe a single site, three-arm RCT which include the two PA interventions EXE and MOT	Investigation of the effects of EXE and MOT compared to CON on MVPA and complimentary PA outcomes	Assessment of implementation and mechanisms of impact of EXE and MOT
Study population	N=220	N=220	Quantitative study population: N=220 Qualitative study population: N=20
Methods	Study protocol	Randomised controlled trial	Mixed methods process evaluation
Results	NA	EXE was more effective than CON to implement MVPA during pregnancy. MOT was not more effective than CON. MVPA in the intervention groups did not reach the recommendations.	Participants reached were highly educated with high autonomy. Interventions were well delivered with high fidelity. Participation in EXE required flexibility and priority. PA perception differed among EXE and MOT.

Table 1. Overview of the three papers included in the present PhD thesis.
EXE, Structured supervised exercise training; MOT, Motivational counselling on physical activity; MVPA, moderate-to-vigorous intensity physical activity; PA, Physical activity; RCT, randomised controlled trial.

Background

This section presents the theoretical framework of the thesis and includes a presentation of the literature on PA in pregnancy and the challenges in implementing PA among pregnant women. The first part of the background involves the area of PA in pregnancy, whereas the last part encompasses evaluation of complex interventions.

The importance of physical activity during pregnancy

Physical activity is significantly associated with health benefits for pregnant women[1–3]; it reduces gestational weight gain[9–12], and the rates of gestational diabetes mellitus, gestational hypertension, preeclampsia, preterm delivery and caesarean section[11,13–15]. Moreover, PA during pregnancy is associated with lower maternal depressive symptoms and improved quality of life, both prenatally and during the postpartum stage[16–20]. It is well-established that PA at a moderate intensity level during pregnancy is safe for women with uncomplicated pregnancies and does not increase the risk of miscarriage[21], preterm delivery[13,22] or complications during delivery[21–23]. Among healthy low-risk pregnant women, PA at vigorous intensity conducted into the third trimester also appears to be safe[24]. In addition, regular aerobic exercise during pregnancy has been shown to improve or maintain physical fitness[25]. Only few safety precautions are outlined. In general, pregnant women are recommended to avoid activities which involve physical contact or the danger of falling[1,3,4]. In a Danish context, activities such as handball, football and horse riding could be included in these safety precautions. However, it should be considered whether no engagement in these activities would lead to less or no activities at all. The 2019 Canadian guideline for PA throughout pregnancy recommends pregnant women to avoid non-stationary biking as such activity may carry a higher risk of falling. A cross-sectional study by Broberg et al. from 2015 revealed that bicycling was the most preferred type of PA before pregnancy (39%) and during early pregnancy (30%) among the 7,915 women participating in the Copenhagen Pregnancy Cohort[26]. Despite a higher risk of falling due to changes in centre of gravity and the ability to respond to unpredictable environment such as traffic or unsteady surfaces as pregnancy progresses, this risk must be weighed against the risk of not engaging in PA.

Physical activity patterns during pregnancy

Notwithstanding the substantial evidence on the benefits of PA during pregnancy, several studies have estimated that most pregnant women (>50%) do not participate in PA as recommended, but the prevalence reported varies across studies and geographical settings. An overall assumption is that 60-

95% of pregnant women do not engage in PA as recommended[3,26–31]. In addition, a considerable decline of PA has been reported both during pregnancy as well as from the preconception period into the pregnancy[27,32]. In 2015, 38% of 7,915 first trimester pregnant women subjectively assessed themselves to meet the PA recommendation[26], but the prevalence of PA during pregnancy has not been updated since. Demographic predictors of higher prenatal PA include being nulliparous and having a higher educational level as well as higher income[33,34].

Physical activity intensity during pregnancy

Over generations the scientific basis of PA recommendations in pregnancy has developed, and the PA advice, targeting pregnant women, has changed accordingly. In the middle of the 20th century American pregnant women were encouraged to engage in housework, gardening and in short, daily walks. In addition, they were occasionally recommended swimming sessions while discouraged to participate in sports. Since then, the prenatal exercise recommendations have been updated several times and as mentioned earlier, pregnant women with uncomplicated pregnancies are now advised to engage in PA at moderate intensity[1,4]. In 2020, ACOG recommended that the PA intensity in the first trimester is safe and effective if performed at less than 60-80% of the age-predicted maximum maternal heart rate or perceived as 12–14 on the rating of perceived exertion scales, the Borg scale[35]. ACOG add that the heart rate should not exceed 140 beats/min, which is a recommendation that has not been addressed since 1985[2,36,37]. Recently, some of the challenges in monitoring absolute and relative exercise intensity in relation to the recommendations from ACOG were discussed[37]. The authors emphasised that the PA intensity measured by using the heart rate estimated from age alone, or from age and a resting heart rate, may cause inaccurate measurements and suggested a wrist-worn PA tracker to collect heart rate data over an extended period of time. They argued that the heart rate is higher during pregnancy compared to a non-pregnant state and that the average resting heart rate increases from early pregnancy to delivery with a reduced submaximal exercise as a result.

Physical activity types during pregnancy

Pregnancy PA trends have been examined during the last decades[38–40]. Recently, results from the Norwegian-Swedish Mother-Childbirth Cohort[30] showed that the majority (n=1,660 (71%)) of the 2,349 included pregnant women answering an electronic questionnaire at their 18th week of gestation had engaged in PA in the last two weeks. The most frequently reported PA performed with higher levels of intensity and duration at least once a week in pregnancy was strolling (n=1,787 (76%)) and brisk walking (n=1,274 (54%)), followed by strength training (n=707 (30%)), bicycling (n=522

(22%)) and jogging (n=313 (13%)). The same types of PA were reported performed twice a week including strolling (n=1,369 (58%)), brisk walking (n=839 (36%)), bicycling (n=361 (15%)), strength training (n=322 (14%)) and jogging (n=127 (5%)). The different types of PA reported by Carlsen et al.[30] were partly in line with findings from the Danish National Birth Cohort published in 2012 including 88,000 pregnancies from 1996 to 2002[41]. Approximately one-third of the women reported some type of exercise at gestational week 16 (n=32,354 (37%)) and week 30 (n=24,639 (30%)), mostly performed as low-impact activities, such as swimming or bicycling[41].

Attitudes, enablers, and barriers to physical activity during pregnancy

To improve pregnant women's participation in PA, it is important to understand their attitudes towards PA, the reasons why they are not physically active and enablers that can be harnessed to design effective PA interventions. A systematic review from 2018[29] investigated attitudes, barriers and enablers to PA reported in 47 quantitative and qualitative studies that included pregnant women with a diverse range of age, gestational age (GA), parity, body mass index, ethnicity and educational and socioeconomic backgrounds. Most of the studies reported positive attitudes towards PA during pregnancy and perceived PA as important, beneficial and safe. Intrapersonal factors towards PA during pregnancy were the most frequently reported enablers and these comprised of maternal and fetal health and well-being, less pregnancy discomfort and easier labour and delivery. In addition, improved fitness and physical appearance were reported as important enablers towards PA. The most frequently reported barriers towards PA were, as with the enablers towards PA, intrapersonal and comprised of fatigue, lack of time and pregnancy discomfort such as nausea, pain and awkwardness due to weight gain and increasing size. Safety concerns such as what type and the intensity of PA to engage in were reported less frequently. A literature review from 2017[42] of perceived barriers to leisure-time PA during pregnancy included 12 quantitative and 14 qualitative studies. The review also reported that intrapersonal barriers were the most frequently cited but added to the above-mentioned barriers, that lack of motivation was one of the most frequently mentioned barriers towards PA. Noticeable, despite the available information on the benefits of PA during pregnancy, women experience contradictory information on PA during pregnancy and barriers to exercise during pregnancy still include safety concerns and uncertainty of what type of PA to engage in[29,43].

Declining physical activity during pregnancy

Over the last decades pregnancy has been seen as a time of natural decline in PA[32,40,44–47]. However, the prevalence of PA varies among different studies; in 2015, a cross sectional study including 1,279

pregnant women[47] found a lower PA prevalence during pregnancy rather than before (p=0.01). One-fourth of the women reported that they were physically active during preconception. However, more than half of these women (55%) stopped exercising due to pregnancy, 29% reported that they maintained their PA level during pregnancy and 16% continued being physically active but with a lower intensity and frequency. The PA prevalence was lowest in the first and third trimester with 14% and 13% of the women performing regular exercise (twice or more per week, at least 30 min/session). In the second trimester, the prevalence of PA was 18%, but only 8% of the women were physically active throughout the entire pregnancy. In 2020, a cross-sectional study including 9,345 pregnant women[48] found a higher PA prevalence than reported by Nascimento et al.[47], as 52% of the women reported that they performed some kind of exercise during pregnancy. 90% of the women being physically active stated that they were physically active in the first and the second trimester and 77% physically active in the third trimester.

Reducing the decline in physical activity during pregnancy

The declines just described were reported in observational studies without any PA interventions. In a systematic review of PA interventions during pregnancy from 2013[32], eight of ten studies included demonstrated higher PA in intervention groups compared to controls. In half of the studies included, PA increased among women in intervention groups compared to controls, and in three of the studies PA decreased less in intervention groups compared to controls. Two studies demonstrated that PA was higher in the control group compared to the intervention group. The review suggested that interventions focusing on PA behaviour can reduce the decline or even increase PA during pregnancy.

Strategies towards physical activity implementation during pregnancy

The contradictory pattern of positive attitudes towards PA, but a low PA participation, has given rise to several PA intervention designs that potentially can improve PA behaviour. A systematic review of PA behaviour change interventions during pregnancy[32] presented several behaviour change techniques of which the most effective appeared to be goal setting and planning with feedback, typically in face-to-face meetings. A meta-analysis of PA interventions for healthy non-pregnant adults included 27 studies providing PA and PA self-efficacy data. The mean age of all participants was 43 years, and 69% of the included participants were women[49]. Similar results were found in a meta-analysis among a non-pregnant population[49]; adults who engaged in PA interventions with action planning (corresponding to 'planning' in the review of Currie et al.[32]) had a significantly higher PA level as well as higher PA self-efficacy compared to interventions without integration of this

technique. Action planning was defined by the authors of the meta-analyses as 'a specific detailed planning of when, where and how the specific behaviour is going to be performed'.

A recently published systematic review[50] on how to promote PA during pregnancy included 15 studies with 5,633 pregnant women. Despite few and varying findings, the authors suggested incorporating newer technologies such as PA applications. However, they pointed out the importance of such devices not standing alone.

Engagement in physical activity research during pregnancy

Over the years, pregnant women have been underrepresented in clinical research. A systematic review from 2017[51] found that on average 40% of invited women refused participation in interventions to improve PA during pregnancy. A qualitative case-control study from 2015[52] revealed that pregnant women felt uncertain about whether participation in interventions could harm their unborn child. In contrast, the possibility of an improved outcome for the baby was reported as the main motivation for trial participation in a qualitative study from 2006[53]. In 2018, a systematic review[54] demonstrated that pregnant women were willing to participate in research particularly for altruistic, e.g., contributing to research and willingness to help future pregnant women in general, and personal reasons, e.g., a desire to improve health behaviour. The barriers for participation were primarily related to inconveniences that encompass practicalities such as time investments and distance to the study site and physical inconveniences such as physical distress, all barriers similar to those reported by non-pregnant populations[55]. In addition, the willingness among the general population to participate in clinical research was also associated with prior experiences in research participation, younger age and higher levels of education.

Randomised controlled trials on physical activity during pregnancy

Table 2 will provide an overview of the last decade's randomised controlled trials with PA interventions during pregnancy with components similar to the interventions in FitMum. In brief, the two intervention strategies applied in FitMum were structured supervised exercise training (EXE) and motivational counselling on PA (MOT). The first section contains five studies with PA exercise components like the ones in EXE, whereas the second section includes six studies with components of PA counselling like ones in MOT. The studies are presented chronologically in both sections. Six studies included objective methods and are highlighted with an orange colour, whereas five studies included subjective methods and are highlighted with a green colour. Studies with a combination of lifestyle, dietary and PA intervention(s) are only included if the main focus was on PA. In brief, the

studies varied in designs and results. Most studies (no matter design) found that the intervention group was more physically active than the control groups. However, the positive results were only found in few of the PA components measured.

Author, year	Participants	Intervention strategies	Method used to determine PA	Results (PA)
Studies with components like EXE				
Oostdam et al., 2012[56]	121 pregnant women: GA at inclusion: <20 weeks Risk of gestational diabetes mellitus	Intervention group (n=62): Group exercise training with 60 min aerobic and strength exercises twice/week Control group (n=59): Standard care	Accelerometer (ActiGraph): Baseline (~15 weeks of gestation) GA 24 GA 32	No significant differences in MVPA (min/week) between groups.
Leung Hui et al., 2014[57]	113 pregnant women GA at inclusion: <20 weeks	Intervention group (n=57): Instructed PA sessions 3-5 times/ week, 30-45 min/session (group and home-based video sessions from inclusion to GA 36 Control group (n=56): Standard prenatal care	PARMedX form for pregnancy: Baseline Two months after baseline	Women with pre-pregnant BMI ≤24.9 had higher PA two months post-intervention (intervention group: baseline 1.4±0.81 units vs. two months after, 1.87 ± 0.35 units, p<0.05).
Poston et al., 2015[58]	1555 pregnant women GA at inclusion: 15-18 weeks + 6 days	Behavioural intervention (n=783): Eight health trainer-led sessions once/ week Control group (n=772): Standard antenatal care	IPAQ: Baseline GA 27-28 weeks + 6 days	Intervention group has higher MET min/week at GA 27-28 weeks + 6 days vs. controls (1836 (792-4158) vs. 1386 (639-363), p=0.002), which was attributable to more time spent walking.

Seneviratne et al., 2016[59]	**74 pregnant women:** **GA at inclusion: <20 weeks** **Overweight/obese**	**Intervention group (n=37):** **Home-based, prescribed moderate-intensity stationary biking. 3-5 sessions/week at 15-30 min/session for 16 weeks** **Control group (n=37):** **Standard care**	**Cycle ergometer (a sub-maximal graded exercise test):** **GA 35**	**Intervention group improved their aerobic fitness and peak workload vs. controls (+48.0 seconds; p=0.019 and +8.8 W; p=0.019).**
Wang et al., 2017[60]	300 pregnant women: GA at inclusion: 10 weeks Overweight/obese	Intervention group (n=150): Supervised exercise 3 times/week (>30 min/session via a cycling program from 3 days after randomisation until GA 37. Control group (n=150): Standard prenatal care	IPAQ: Baseline GA 25 GA 36	Intervention group had higher total METmin/week vs. controls at GA 25 (1741±798 vs. 1327±1300, p=0.010) and higher moderate-intensity PA at GA 25 (484±220 vs. 64±360, p<0.001) and GA 36 (436±177 vs. 81±239, p<0.001).
Studies with components like MOT				
Gaston et al., 2012[61]	60 pregnant women: GA at inclusion: GA 13-31 Inactive	Protection motivation theory (PMT) + action-planning (n=21): Educational material on PA and PA action-planning sheets PMT + action- and coping-planning (n=19): Educational material on PA, PA action-planning sheets and coping strategies PMT-only (n=20):	Accelerometer (ACTICAL) and self-reported exercise: Baseline 1 week post-intervention 4 weeks post-intervention	All participants reported increased exercise from baseline to 1 week post-intervention. Participants in both planning groups were more active (p<0.001) than those in the PMT-only group by 4 weeks post-intervention (by accelerometer).

		Educational material on PA during pregnancy		
Aittasalo et al., 2012[62]	339 pregnant women: GA at inclusion: 16-18 weeks At risk for gestational diabetes mellitus	Intervention group (n=219): 5 PA counselling sessions, monthly group PA-meetings, telephone counselling 1 week after each meeting Control group (n=180): Standard care including PA counselling at the first maternal visit	IPAQ: Baseline GA 26-28 GA 36-37	No significant difference in leisure time PA between groups.
Renault et al., 2013[63]	425 pregnant women: GA at inclusion: <16 weeks BMI ≥30 kg/m^2	Intervention group 1 (n=142): PA plus dietary intervention with follow-up on dietary advice and PA encouragement Intervention group 2 (n=142): PA with encouragement to increase PA Control group (n=141): Standard care	Pedometer (Yamax Digiwalker CW-700/750): 7 consecutive days every 4 weeks	No significant difference in steps/day between groups.
Hawkins et al., 2014[64]	260 pregnant women: Inclusion at 1st trimester At risk for gestational diabetes mellitus	Exercise group (n=143): Individually tailored, motivationally matched self-selected PA in 12 weeks Health and wellness intervention (n=147):	PPAQ: Baseline 12 weeks of intervention	The exercise group had greater increases in sports or exercise activity (METhours/week) compared to health and wellness group (0.3 vs. 5.3, p<0.001), smaller declines in total PA (-42.7 vs. -2.1, p=0.02) and MVPA

		Tips sheets and telephone calls on health and wellness during pregnancy		(-30.6 vs. -10, p=0.05).
Currie et al., 2015[65]	109 pregnant women: GA at inclusion: 8-15 weeks Healthy, primiparous	Intervention group (n=47): Three individually tailored 30-60 min face-to-face PA consultations (one per trimester) Control group (n=50): Standard care	Accelerometer (Actigraph model GT3X): GA 12-15 GA 20-22 GA 35-37	No differences in PA between groups. Moderate and vigorous PA and MVPA declined between trimester one and three in both groups, p<0.001.
Hayman et al., 2017[66]	77 pregnant women: GA at inclusion: 10-20 weeks Healthy	Intervention group (n=39): Tailored PA advice and access to a library of PA papers Control group (n=38): Access to the library of PA papers	Accelerometer (GeneActiv): Baseline Post-intervention (4 weeks intervention).	Intervention group increased MVPA from baseline to post-intervention compared to controls (mean difference in min: 35.87 vs. 9.83, p<0.05).

Table 2. Overview of randomised controlled trials with physical activity interventions during pregnancy.
The trial delivered physical activity interventions with components like EXE or MOT. GA, Gestational age; MVPA, Moderate-to-vigorous intensity physical activity; BMI, Body mass index (kg/m^2); PA, Physical activity; MET, Metabolic equivalent of task; IPAQ, International Physical Activity Questionnaire; PPAQ, Pregnancy Physical Activity Questionnaire.

Monitoring physical activity during pregnancy

The American College of Sports Medicine recommends that exercise intensity is prescribed using either absolute or relative values[67]. The absolute intensity is based on the work performed, including PA, and expressed as the metabolic equivalent task (MET). The individual's cardiorespiratory fitness is not considered even though it may not exactly equal the assigned MET value of a given activity. The relative intensity, in contrast, accounts for the cardiorespiratory fitness and is based on oxygen uptake, perceived exertion or heart rate as measured by the PA tracker[37]. However, absolute intensity can be imprecise, just as obtaining oxygen uptake can be a complex and challenging task. Thus, ACOG suggests monitoring intensity based on heart rate and perceived exertion[2].

One of the most common options available for pregnant women to measure their heart rate is a wearable device such as a PA tracker. For years, a chest strap was the best option for accurately

measuring the heart rate at a low cost. However, the discomfort caused by wearing devices strapped tightly around the thorax made using them over longer periods of time a challenge, especially for pregnant women. Thus, a wrist-worn PA tracker integrating heart rate assessment has gained popularity in recent years. In addition, PA trackers are now being used extensively for research purposes as intervention facilitators and as tool of measurement. The wrist-worn tracker applies an optical measurement method to estimate the heart rate from the pulsatile changes in blood volume near the skin surface[37].

Evaluation of complex interventions

Traditionally, RCTs have been considered the ideal study design for obtaining unbiased estimates of efficacy in PA interventions[68–71]. This is not without reason, since the RCT design provides the means for determining if there is a causal relationship between the intervention (exposure) and in terms of the outcome(s) of interest. The robust, tightly controlled design based on the power of randomisation results in high internal validity. In RCTs in general, interventions are initiated at baseline, and outcome(s) are measured at the end of the study, offering an answer as to *whether* and *not how* the intervention worked. Often, it is hard to recognise how an intervention is expected to work. A poor description of interventions and the surrounding aspects provides insufficient information about any causal processes present in the interventions, creating a black box of which the content is not covered[72]. Research involving complex interventions must go beyond asking whether an intervention works, in the sense of achieving its intended outcome, by asking broader questions to identify any other effects of the intervention[73]. Complex interventions are defined as interventions containing multiple interacting components and often encompassing a wide variety of non-pharmacological mechanisms, particularly those that aim to change behaviour[71,73–75]. As such, many PA interventions can be defined as complex. However, the number of components influences the degree of complexity as well as the targeted behaviour and the implementation of interventions. Further, the complexity exists not only in the interaction of the different components but in the interactions between the intervention and the context in which the intervention is embedded. Most publications on pregnancy PA interventions focused on their efficacy in terms of health and pregnancy outcomes but did not provide a thorough assessment of external validity[32,71,73,75].

Process evaluations of complex interventions on physical activity during pregnancy

Process evaluations aim to clarify how an intervention functions by examining the different implementation paths and the mechanisms of impact[75]. The value of process evaluations within trials of complex interventions is widely recognised, and in the last decades, the literature on process evaluation related to public health interventions has grown considerably. Even though theoretical frameworks have emerged[75–77], there is a great variation in how the process evaluation is planned and conducted. Originally, the process evaluation frameworks included only quantitative measures, but the value of qualitative data as a complement to quantitative measures has now been acknowledged[70,77,78]. In addition, it has even been proposed to integrate qualitative assessments in an expanded mixed methods model to further strengthen the frameworks[69]. A review from 2015[79] of behavioural intervention studies using the widely known process evaluation framework RE-AIM (reach, effectiveness, adaption, implementation, maintenance)[77] revealed that 6-24% (median of 15%) of the studies included qualitative methods to ensure a multi-level insight by examining the process evaluation dimensions. In the research field of PA during pregnancy, only a few process evaluations have been conducted[80,81]. These process evaluations have been applied in large multicentre RCTs published in 2015; the UK Pregnancies Better Eating and Activity Trial (UPBEAT)[82] and the pilot study of Vitamin D and Lifestyle Intervention for gestational diabetes mellitus prevention (DALI)[58] were conducted to prevent gestational diabetes mellitus among overweight and obese pregnant women. Both process evaluations undertook dimensions from the framework of Steckler and Linnan[76]. The process evaluation of UPBEAT[80] combined quantitative and qualitative data and revealed that practicalities often interfered with regular attendance in the delivered sessions even though participants expressed a high willingness to attend. The DALI study[58] found that the intervention was not associated with a significant change in PA among participants and the process evaluation[81] revealed that the DALI study was very time-consuming for the women, which led to lower participation rates.

Rationale for conducting the FitMum randomised controlled trial

Low prevalence of PA during pregnancy has been evident for years, but little attention has been paid to the mechanisms affecting the prevalence. It is necessary to identify and understand the mechanisms involved and make them known so pregnant women can increase their PA level in a safe and effective manner. To gain a comprehensive insight into mechanisms at work in a complex PA intervention

during pregnancy, a mixed methods design was chosen, combining the quantitative PA effect and the perceived experiences with participation.

Aims

The main aim of this PhD thesis was to investigate the effects of offering two different PA interventions to healthy pregnant inactive women on PA level and to explore the implementation and mechanisms of impact focusing on:

- Moderate-to-vigorous intensity physical activity and complementary physical activity outcomes from the randomised controlled trial FitMum (Paper 2)
- Process evaluation components of the two physical activity interventions in FitMum and the pregnant women's perception of their intervention participation (Paper 3)

The predefined hypotheses in Paper 2 were that both EXE and MOT would increase moderate-to-vigorous intensity PA (MVPA) in pregnancy compared to CON, and that EXE would be more effective than MOT as described in the statistical analysis plan for FitMum RCT available at clinicaltrials.gov, #NCT03679130.

Methodological considerations

Paper 1 and 2: FitMum randomised controlled trial

This section will initially present the FitMum RCT in brief. The methodological considerations of the two PA interventions in FitMum RCT and the measurements used to assess PA in FitMum will be placed in the context of international state-of-the-art research within the area of PA in pregnancy.

The FitMum design

The FitMum study was designed as a single-site, three-arm RCT and developed to investigate how inactive pregnant women could implement PA in everyday life. To explore in what way pregnant women could increase their PA level most effectively, we investigated the effects of two different PA interventions on actual PA level. The interventions were developed with inspiration from the 2008 Medical Research Council's framework for developing and evaluating complex interventions[74]. As a part of the development, 27 semi-structured interviews with stakeholders including Danish pregnant women, midwives and obstetricians were conducted (unpublished material) to gain a broad understanding of pregnant women's views of PA, demographics, anthropometrics and varied levels of PA among the pregnant women. A thematic analysis was performed to explore the feasibility of FitMum as well as the motivational factors and barriers to PA during pregnancy. Together with findings from the available literature, the interviews were used to design and structure the two PA interventions. More specifically, and as an example, we asked the pregnant women when they would like to exercise during the day, what kind of exercise they would like to take part in and how a session advantageously should be carried out if they were enrolled in FitMum. Among other things, most of the women expressed that they would like to join a group exercise session just before or just after work. It was important for them to not have to leave home after dinner and when their children were going to sleep.

In brief, the two intervention strategies, EXE and MOT, were compared to a control group (CON) receiving standard prenatal care. The primary outcome was min per week of MVPA from randomisation to gestational age of 28 weeks and 0-6 days determined by a wrist-worn, commercial Garmin activity tracker. Additionally, complementary measures of PA were obtained by the Danish version of the Pregnancy Physical Activity Questionnaire (PPAQ-DK)[83,84] and by 'gold-standard' doubly labelled water technique (DLW)[85–87]. To gain a comprehensive insight into the complex variable that PA and especially PA in pregnancy constitutes, several other outcomes were investigated. We used multiple disciplines and research fields as well as different scientific methods.

The overall study design from inclusion to the follow-up test visit one year postpartum is described in Paper 1 and shown below in Figure 1.

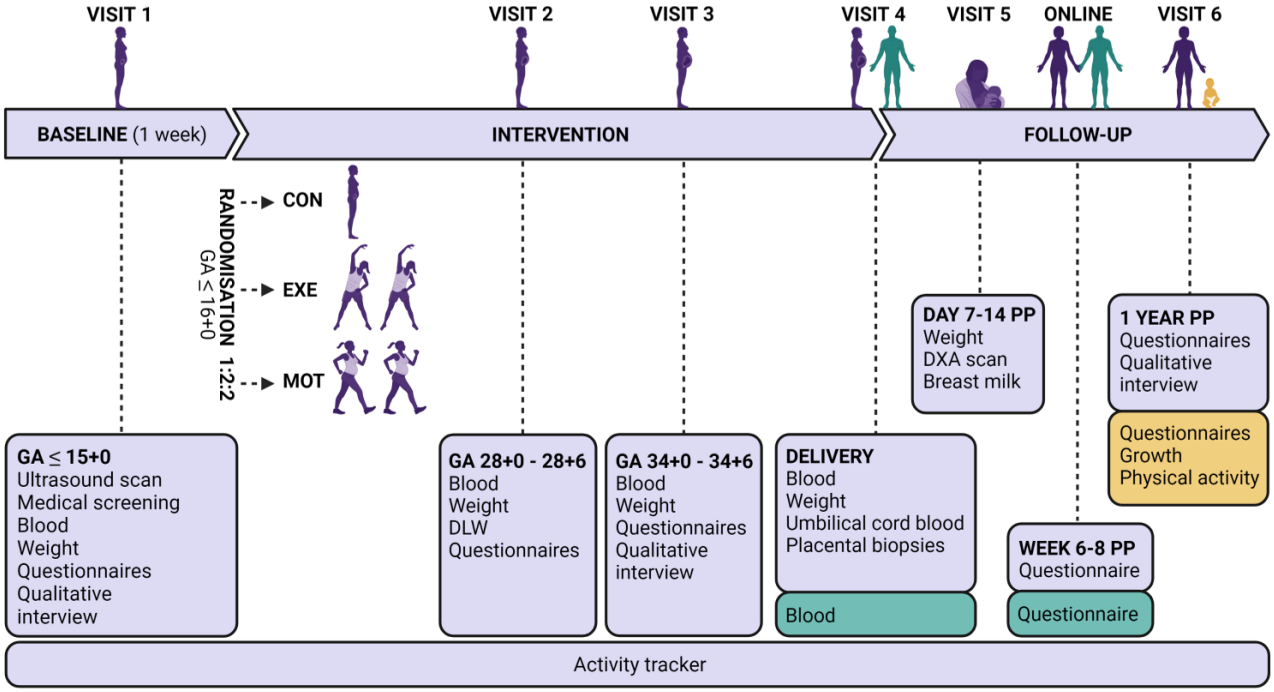

Figure 1. Study design of the FitMum randomised controlled trial.
After inclusion at visit 1, participants completed a one-week baseline period. Data were collected at the hospital three times during pregnancy (visit 1-3), at delivery (visit 4), and two times in the first year postpartum (visit 5 and 6). Data were also collected continuously by the activity tracker and via online questionnaires throughout the study period. Purple, participant; Green, partner; yellow, offspring; GA, Gestational age; CON, Control; EXE, Structured supervised exercise training; MOT, Motivational counselling on physical activity; DLW, Doubly labelled water; DXA, Dual-energy X-ray absorptiometry; PP, Postpartum. The figure is created with Biorender.com.

Methodological considerations of the two physical activity interventions in FitMum

In Figure 2, a programme theory presents an overview of how and under what circumstances EXE and MOT were expected to lead to their effects. The programme theory is created as a single linear causal path even though complex interventions are rarely straightforward[88]. The two first columns cover the planning part of the study; the certain resources needed to operate the study and the two interventions (activities). The remaining columns cover the intended results; the outputs and mechanisms as they are strived for if the planned interventions are accomplished to the intended extent as well as the impact expected to occur if the benefits to participate are achieved.

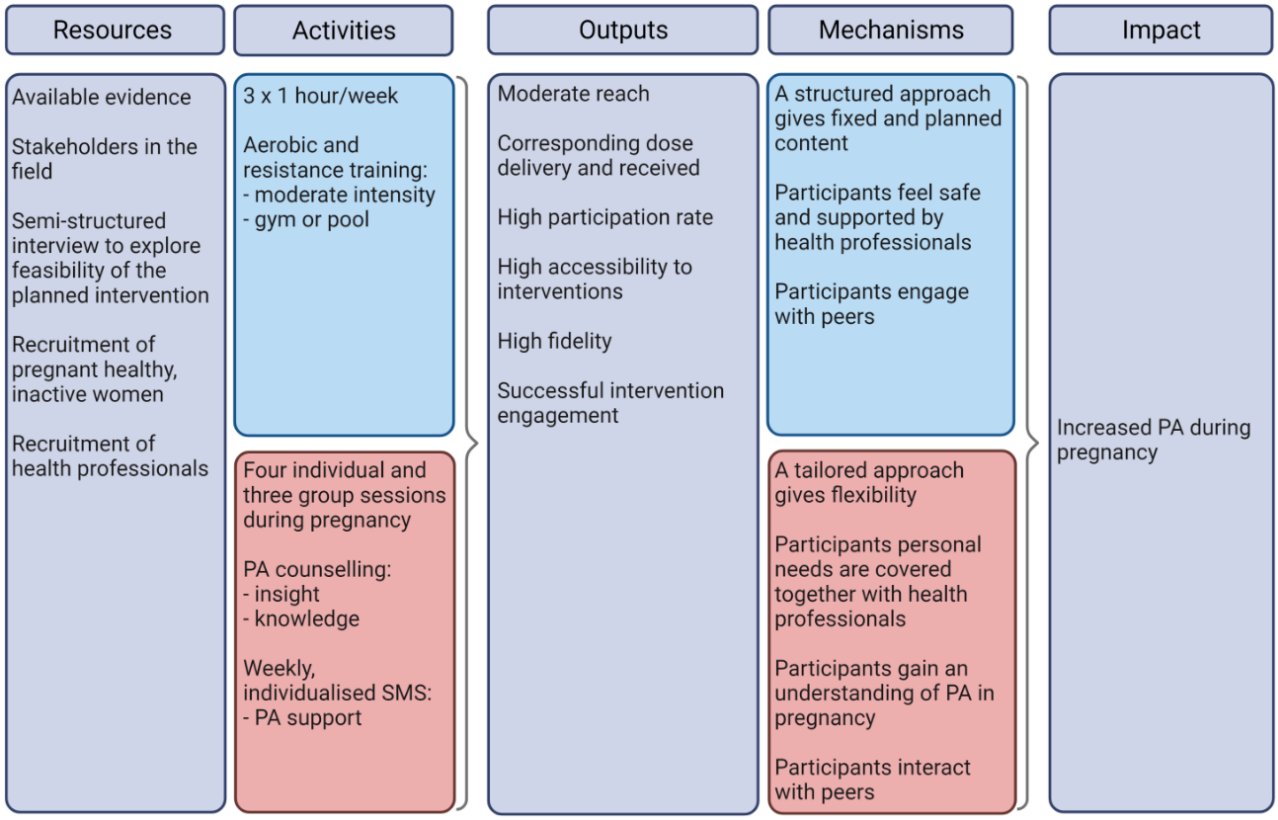

Figure 2. Programme theory of the FitMum interventions.
The purple colour represents both intervention groups, the blue represents EXE and the red represents MOT. PA, Physical activity. The figure is created with Biorender.com.

Structured supervised exercise training

The gym sessions consisted of a combination of aerobic and resistance training with approximately 30 min stationary biking with a combination of hill climbing and high cadence intervals and 30 min of exercise with, e.g., elastic bands or body weight[89]. In general, the woman were recommended a heart rate range of 121-141 beats/min[3] or to a degree where the women is able to maintain a conversation during PA (12-14 at the perceived exertion Borg scale[35]). Resistance training was performed with sets of 10-15 repetitions of each exercise[90]. However, with the use of, e.g., elastic bands, exercise intensity was difficult to quantify specifically. The stationary bike session was inspired by Wang et al.[60] who described their biking session in detail and found that such a session initiated early in pregnancy, and performed no less than 30 min, 3 times/week, was associated with a significant reduction in the frequency of gestational diabetes mellitus in overweight and obese pregnant women. The aquatic session consisted of 15 min of swimming and 45 min of water exercises with, e.g., plates or dumbbells inspired by AquaMama[91]. Adding an aquatic activity was based on findings from a Norwegian cohort study including 34,508 pregnancies and a nested case-control study

within the Danish National Birth Cohort including 5,304 pregnancies[40,92]. Owe et al. found that during pregnancy participation in all types of activities decreased, except for swimming, which was the only activity that increased during pregnancy[40], while Andersen et al. found that swimming was associated with a decreased risk of pelvic girdle pain compared to no exercise[92].

During the COVID-19 pandemic restrictions that were introduced in Denmark on March 11th, 2020, gym and aquatic sessions were converted into a home-based setup. The intension was that the online version should resemble the physical as much as possible. Thus, the online exercise sessions were offered with the same frequency and at the same time as the physical and were a combination of a 30 min offline, self-selected activity such as biking, brisk walking or cardio exercises and a 30 min online, supervised group session such as aerobic and resistance training.

Motivational counselling on physical activity

The content of MOT was inspired by recommendations on lifestyle interventions during pregnancy that support individualised advice on how to increase PA level rather than using a generic approach[93]. In addition, MOT was designed based on previously mentioned barriers and enablers towards PA in pregnancy and the recommendation of implementing a theory-based framework into PA interventions[29,94]. The Self-determination Theory and Motivational Interviewing[95] were applied to help in understanding the PA behaviour. Often, the intrapersonal barriers change during pregnancy, with fatigue and nausea being most dominant in early pregnancy whereas changes in size and shape dominate later in pregnancy[29]. In contrast, PA in early pregnancy was found to be the factor most strongly associated with PA at later gestations[96]. Based on that, the counselling sessions were distributed with most sessions in the beginning of the intervention period (Figure 1, Paper 3). Further, MOT was designed to accommodate individual needs and physical changes during pregnancy as suggested[29]. Participants in MOT were recommended to exercise at the same intensity as participants in MOT (described in the previous section).

Timing of interventions

Over the years, pregnancy has been referred to as a 'teachable moment'[97,98] or a 'window of opportunities'[99]; a period with valuable opportunities for women to improve their health as they may be more receptive to health messages and are in frequent contact with health professionals[13,97,98]. In addition, engaging in PA is viewed by some pregnant women as an opportunity to do something for themselves and as a behaviour that provided some time only for the women herself[100]. In contrast, interventions initiated in pregnancy may be influenced by previously mentioned barriers towards PA,

e.g., nausea and weight gain[29]. In addition, pregnancy is perceived by some women as a period in which they are exempt from bodily ideals that some women aspire to achieve, and therefore do not have a need to be active[100]. Interventions initiated as early in pregnancy as possible may provide basis for a long intervention period. However, interventions initiated early in pregnancy will increase the risk of recruiting women who may later miscarry which may increase the required sample size[93]. Pregnancy is a relatively short time span, and succeeding with a lifestyle behaviour change may take longer time[93]. Thus, it may be important to recognise the preconception as a unique stage of life which will provide a longer time horizon for habit formation[93,101].

The primary outcome in FitMum

Choice of primary outcome in FitMum

PA at moderate intensity was prescribed in both interventions in FitMum according to the current recommendations from the Danish Health Authorities[4]. In addition, the recommendation prescribes that the woman can continue being active at vigorous intensity if she has been active at this intensity prior to pregnancy. Hence, MVPA was chosen as the primary outcome in FitMum. As mentioned previously, walking is one of the most common types of PA chosen in pregnancy. Some studies even indicate that walking is the most preferable activity during pregnancy[30,48,102]. Taking into consideration that walking realistically could be ingrained within pregnant women's various daily activities, e.g. through transportation, occupation and leisure time, number of steps could have been chosen as the primary outcome. Due to the current recommendations, it was important to separate walking from activities with higher intensity. In general, a cadence at 100 steps/min is prescribed for adults to achieve moderate intensity PA[103]. That entails at least a brisk walk and will exclude, e.g., stroller walking, walking with children and walking with lower intensity in general. In addition, approximately 50% of women experience low back or pelvic girdle pain during pregnancy[104], and it must be assumed that some of these women would prefer non-weightbearing activities, e.g., biking or swimming, which are also some of the most preferred activities in pregnancy[30,48]. On that basis and due to the PA recommendations during pregnancy[4], MVPA was chosen as the primary outcome.

Sample size

The sample size needed to demonstrate an overall significant difference with a power of 80% and a significance level of 5% was determined for the primary outcome of the study, MVPA from randomisation to the 29th gestational week, and determined to 220 participants. Participants were randomised into CON, EXE, or MOT in a 1:2:2 ratio. Essentially, more women were needed in the

intervention groups to compare those, as we expected less difference in MVPA between EXE and MOT than between CON and EXE and CON and MOT, respectively. In addition, we assumed that the unequal randomisation would be more attractive for purposes of recruitment because participants had a higher chance of being randomised to EXE or MOT. It was assumed, that participants were motivated for PA and an unequal randomisation provided a greater chance of being randomised to EXE or MOT. When the sample size had to be determined, there was no obvious literature available on what effect size and SD to expect on PA assessed with the novel commercial activity tracker chosen to measure the pregnant women's physical activity. Therefore, the average weekly PA was estimated to 60, 210 and 150 min/week in CON, EXE, and MOT, respectively and determined the SD to be 116 min/week based on a study consisting of similar PA intervention during pregnancy which measured PA with accelerometers[56]. The weekly MVPA of 210 min/week was based on the Danish recommendations on PA during pregnancy[4]. Due to the predefined hypothesis in Paper 2, we assumed that EXE would be more effective than MOT and that MOT would be more effective than CON. Thus, we stipulated the average weekly MVPA in MOT to 150 min/week inspired by the international recommendations on PA during pregnancy[1]. The average weekly MVPA of 60 min/week which was estimated in CON, was based on the PA exclusion criteria in the FitMum study[89].

Measurements used to assess physical activity in FitMum

The following section is based on the PA measurement tools used to assess PA in the FitMum study which is presented in Paper 2. It includes the objective methods PA tracker and DLW, and the subjective questionnaire PPAQ-DK, which gives a comprehensive insight into the complex variable that PA constitutes.

Physical activity tracker

Commercial PA trackers have the potential to allow for population-level measurement of PA and large-scale behaviour change. However, questions remain about their reliability and validity. Developing FitMum we tested activity trackers from Fitbit, Garmin and Polar. Polar was best at measuring heart rate on the wrist, but Polar's Application Programming Interface (API) did not allow data transfer to a database. The Fitbit design was not as appropriate as Garmin with its soft strap.

No reviews examined the validity and reliability of the Garmin Vivosport, but other Garmin PA trackers and other PA trackers brands have been included. The most recently published systematic review from 2022[105] found that trackers like Garmin Vivosport captured ≥75% of data when the PA

tracker was worn. For PA trackers comparable to Garmin Vivosport, the mean absolute percentage error for measuring heart rate ranged from 2% (SD 1.5%) to 17% (SD 20%). A review from 2020[106] summarised the validity and reliability of 32 PA trackers from Garmin exclusively and found that very few studies had reported validity and reliability of heart rate and intensity. The findings indicated that heart rate validity varied widely from low to excellent in the correlation coefficient and exceeded the acceptable limits in the mean absolute percentage errors. The validity and reliability of steps was good. A systematic review from 2020[107] found that commercial PA trackers are accurate for measuring steps and heart rate in laboratory-based settings, but they emphasised the variations among brands and PA tracker type. Recognising the advantages and disadvantages using PA trackers as a measurement tool for PA, a combination of heart rate assessment and perceived exertion was suggested as the current best way to monitor PA intensity in pregnancy[37]. In 2020, a cross-validation study[108] determined and validated ratings of perceived exertion for different PA intensities derived from the recommended heart rate ranges in the 2019 Canadian Guideline for PA throughout pregnancy. It was suggested that pregnant women can monitor their exercise intensity during pregnancy, rating the perceived exertion according to Borg[35] as participants in both EXE and MOT in FitMum were recommended to. The Borg scale[35] is the most widely used scale and useful in PA intensity monitoring. The scale was developed as an attempt to provide a user-friendly measure that increases linearly with intensity, similar to the responses of heart rate[35].

Doubly labelled water

DLW is considered as gold standard to assess free-living total energy expenditure due to its high degree of accuracy. By measuring the disappearance rate of labelled isotopes in urine samples it estimates carbon dioxide production and can be used to estimate total energy consumption with high accuracy[109]. This non-invasive process imposes minimal burden to participants. However, it is expensive and can rarely be applied on a large scale[110]. It is worth mentioning that DLW measures energy expenditure and not PA. Even though energy expenditure and PA are highly correlated, they may vary. DLW does not provide specific information on daily PA nor the activity type, intensity or duration of PA[111]. However, the active energy expenditure (total energy expenditure minus basic metabolic rate) is considered to represent energy expenditure in response to PA. DLW has previously been used in pregnant women[112,113], and it has been concluded that the method is as valid in pregnant as in non-pregnant women[114]. However, the PA level in pregnant women is not fully comparable to non-pregnant women as PA will represent a relatively smaller share of total energy consumption when BMR is increased[113,114].

Pregnancy Physical Activity Questionnaire

Participant-reported measurements, typically in the form of PA recall questionnaires, are often used as an alternative to objective measurements because of their time and cost effectiveness[115]. In general, questionnaires are easy to administer and have a low cost of use, though the inherent bias of a participant reported outcome measure is inevitable. Questionnaires rely on people's memory and willingness, which entails a risk of recall bias and social desirability. As PA is recommended by health authorities, participants may be inclined to overestimate the duration or intensity of the activity performed[116,117]. Only few questionnaires are considered as valid tools for measuring PA in pregnancy. Of those, the Pregnancy Physical Activity Questionnaire (PPAQ), developed by Chasan-Taber et al., is considered one of the most valid and reliable[83,116]. PPAQ is designed to determine frequency, duration and intensity of total PA during any trimester in pregnancy[83]. It has been translated and culturally adapted to other nations and languages[118–120]. Prior to the FitMum study, we translated the original version of PPAQ into Danish (PPAQ-DK)[84] and found it to be valid and reliable to measure PA in pregnant Danish women. The total PA was found to be the most valid component. In FitMum, PA was digitally self-reported by participants using PPAQ-DK at baseline, visit 2 and visit 3, respectively[89]. Overall, there was a high willingness to complete PPAQ-DK among participants included in FitMum. At baseline, all participants completed the questionnaire; at visit 2, 100% of CON, 99% of EXE and 96% of MOT completed; and at visit 3, 91% of CON, 99% of EXE and 90% of MOT completed. A limitation is that it is unknown whether the administration of PPAQ-DK may have led to a heightened awareness of PA among participants[116], especially in MOT who received a thorough review of their PA level at the counselling sessions.

Paper 3: A mixed methods process evaluation of physical activity interventions during pregnancy

In this section the methodological considerations of complex interventions, the applied process evaluation framework and mixed methods intervention design will be placed in the context of international state-of-the-art research within the area of process evaluation of complex PA interventions.

Complex intervention evaluation

The research field of complex interventions develops quickly, and a new standardised framework for developing and evaluating complex interventions was published in 2021[71,73] (Figure 3).

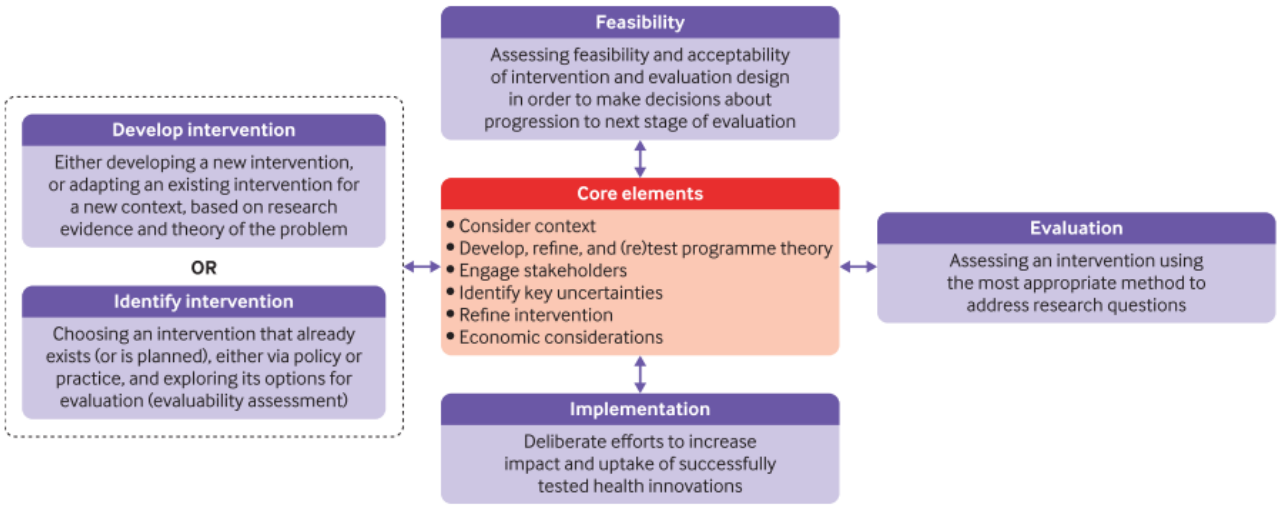

Figure 3. The 2021 framework for developing and evaluating complex interventions.
The new framework is commissioned jointly by the Medical Research Council and the National Institute for Health Research[73]. The figure is reproduced with kind permission from Dr. Kathryn Skivington.

The framework divides complex intervention research into four phases: development or identification of the intervention, feasibility, implementation, and evaluation. The evaluation forms the basis of the present PhD thesis. The pathway through the research process is intended as non-linear and iterative. Each phase is associated with a set of key elements that include context, development and refinement of programme theory, stakeholder engagement, identification of key uncertainties, refinement of the intervention and economic considerations[71,73].

The Medical Research Council framework for process evaluations

The Medical Research Council process evaluation framework developed by Moore et al.[75] (Figure 4) is widely recognised. The framework supports a clear reporting of the interventions and its causal assumptions, information about context, implementation and mechanisms of impact and the outcomes. Insights from the framework can provide knowledge about, e.g., the proportion of the target group that intervened with the interventions and to what extent the interventions were implemented as intended[51,69,75].

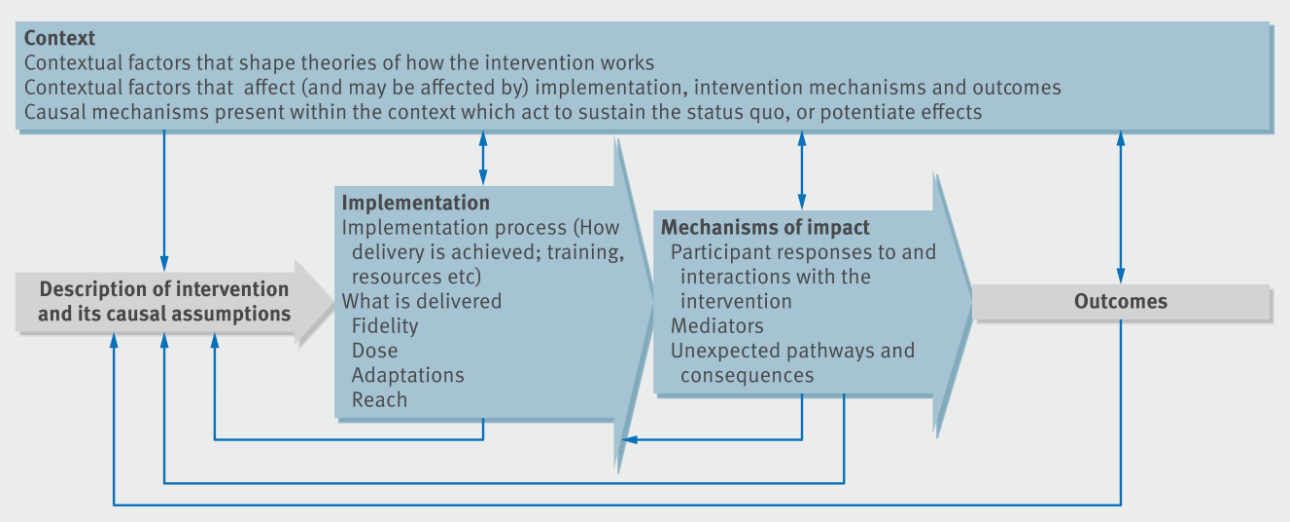

Figure 4. Key functions of process evaluation.
Blue boxes are the key components of a process evaluation and the arrows connect the relations among them[75]. The figure is reproduced with kind permission from Professor Graham Moore.

Mixed methods intervention design

Over the years, various definitions of mixed methods research have been proposed by different mixed methods scholars[121]. This thesis is inspired by Creswell and Clark[122] and considers mixed methods as an approach to research in behavioural and health sciences in which both quantitative and qualitative data are collected, integrated and interpreted based on the combined strengths of both sets of data to understand the research problem. The mixed methods intervention design[122] (Figure 5) was chosen with the intent of adding qualitative data into a quantitative research design to improve personal and contextual experiences drawn from the participants included in the FitMum study along with the quantitative outcome measures. The design was originally named as the mixed methods experimental (or intervention) design. However, for this purpose, the word 'intervention' is used instead of 'experimental'. In the present PhD, the qualitative interviews were conducted in the last part of the intervention (at the 35th gestational week) to understand how participants experienced the interventions (a convergent core design) and separately analysed after the quantitative data analysis to understand the impact of the quantitative data (an explanatory sequential design). The integrated analysis assessed the relationship between the quantitative and qualitative data, i.e., whether the two types of data reinforced each other, expanded upon each other, or were discordant with one another. The mixed methods intervention design was chosen acknowledging that the quantitative approach in Paper 2 might simplify the mechanisms and that a more open and flexible qualitative approach was needed to gain a more comprehensive understanding of the mechanisms at work in relation to participating in the FitMum interventions.

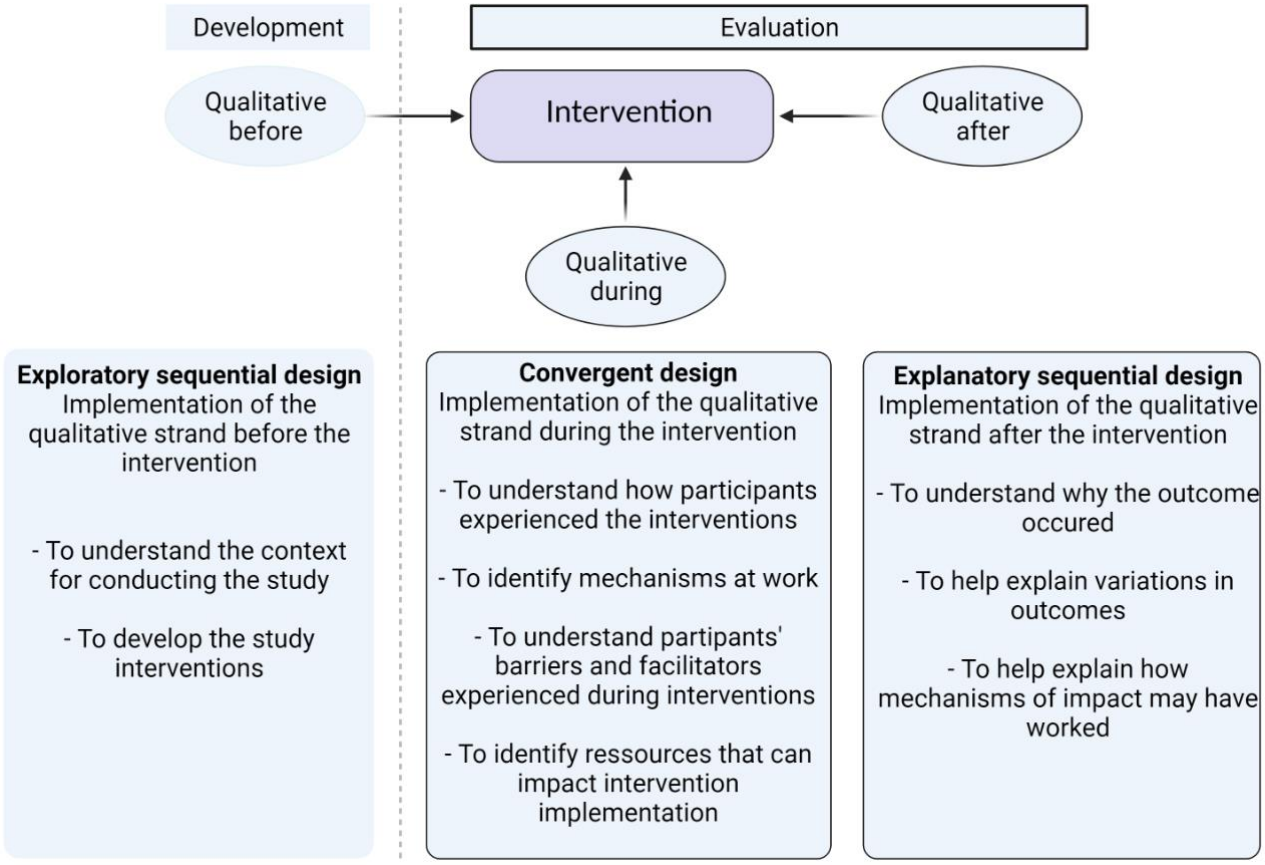

Figure 5. Mixed methods intervention design.
The illustration is created in relation to the FitMum study based on the Creswell and Clarke method[122]. The figure is created with Biorender.com.

Results and discussion

This section will initially present the main results of the effect evaluation of the FitMum study (Paper 2) and place them in a discussion with the context of international state-of-the-art research within the area of PA in pregnancy. Thereafter, the processes of the FitMum study interventions (Paper 3) will be assessed in the same way.

Paper 2: The effect of the FitMum randomised controlled trial on physical activity

Inclusion in FitMum

Two hundred and twenty healthy, inactive, pregnant women were included in FitMum. The flow of inclusion, randomisation, and analysis are presented as Figure 1, Paper 2. To meet the determined sample size, the inclusion ran for two years. In that period, written study information was electronically addressed to 8245 women who attended a first-trimester ultrasonic scan at Nordsjaellands Hospital. On their own initiative, 872 women (11% of 8245 women) completed an online questionnaire and hence pre-screened for eligibility. Of those, 284 women remained eligible for further assessment and were screened for inclusion at visit 1. GA at inclusion ranged from 6+1 to 15+0 weeks (Table 1, Paper 2). One participant was lost to follow-up before randomisation; hence 219 women were randomised to one of the three groups one week after inclusion (CON: n=87, MOT: n=87, CON: n=45). Overall, the penetration was 3.4% (284 of 8245 women), and participation was 77.5% (220 of 284 women). Penetration was calculated as the number invited divided by the estimated target population, and participation was calculated as the number included divided by the number invited, converted to percentage[123]. The lost to follow-up rate was lower than expected (15% from randomisation to the 29th gestational week and 19% at delivery).

Transparency in inclusion

In general, the inclusion rate is well reported in RCTs including PA interventions during pregnancy[51]. In studies comparable to FitMum, 16-37% of the pregnant women assessed for eligibility were actually included[58,60,124,125]. In the FitMum study 25% (220 of 872 women) of all women who showed interest in FitMum were included. Given the low engagement in PA interventions[51], examination of the representativeness of participants and non-participants is important to raise the level of generalisability and it may help in the development of interventions for specific populations. In FitMum, 7373 women (89% of women who delivered at Nordsjaellands Hospital in the study period)

did not complete the online screening questionnaire, but we did not have permission to ask why they did not interact. Based on this, the pre-screening questionnaire presented in Paper 1 was useful.

Participants

Participant representativeness

Participants in FitMum all lived in North Zealand. Inhabitants in this region are in general comparable to inhabitants in large parts of Denmark in terms of educational and occupational level and ethnicity. However, people in this region tend to have higher average household income[126]. Despite this, the study population was expected to be relatively representative. A comparison between the characteristics between women randomised in FitMum (Table 1, Paper 2) and all women who delivered at Nordsjaellands Hospital in 2017 (n=4,011) (not published data) showed no differences in age (FitMum: 31.5±4.3 years at inclusion, overall: 31.1±5.2 years at delivery), pre-pregnancy body mass index (FitMum: 24.1 (21.8-28.7) kg/m2, overall: 23.1 (17.8-36.6) kg/m2) and nulliparity (FitMum: 37%, overall: 44%). By contrast, participants in the FitMum study were higher educated (Paper 3). As the willingness to participate in clinical research is associated with, e.g., higher levels of education[55], we must assume that there is risk of a selection bias in FitMum. In addition, it is well-known that PA self-efficacy is the clearest correlate associated with participation in PA among adults[127]. Thus, we may assume that women volunteering for a PA intervention studies like FitMum are motivated for PA. A higher educational level might also cause a higher level of flexibility in work life which was derived from the qualitative analysis presented in Paper 3. It is unknown whether the interventions would have caused the same effects if they were implemented in other regions of Denmark or especially in other countries influenced by different contexts, e.g., as socioeconomic or commuting.

Future recommendations for contraindications for physical activity during pregnancy

We included healthy pregnant women with no obstetrical complications, since they are advised to be physically active[1,4]. New classifications for absolute and relative contraindications for engaging in prenatal PA have recently been proposed[128]. It is suggested that current complications such as hypertension, short cervix and multiple pregnancies should no longer be classified as contraindications to PA as evidence shows no harm of exercise. On the contrary, prenatal PA for women with the mentioned complications may in fact be beneficial for maternal and fetal health outcomes. For pregnant women with relative contraindications such as mild respiratory disorders and mild preeclampsia it is suggested that they could engage in modified MVPA. However, pregnant

women with more serious PA contraindications such as severe respiratory disorders and placental abruption, should still avoid MVPA but maintain daily acitivties[128].

Adherence to physical activity interventions during FitMum

Structured supervised exercise training

Throughout the study period participants randomised to EXE participated in less than half of the three weekly recommended sessions (Paper 2). The average weekly attendance in EXE during the entire study period (including physical and online sessions) is presented in Figure 6.

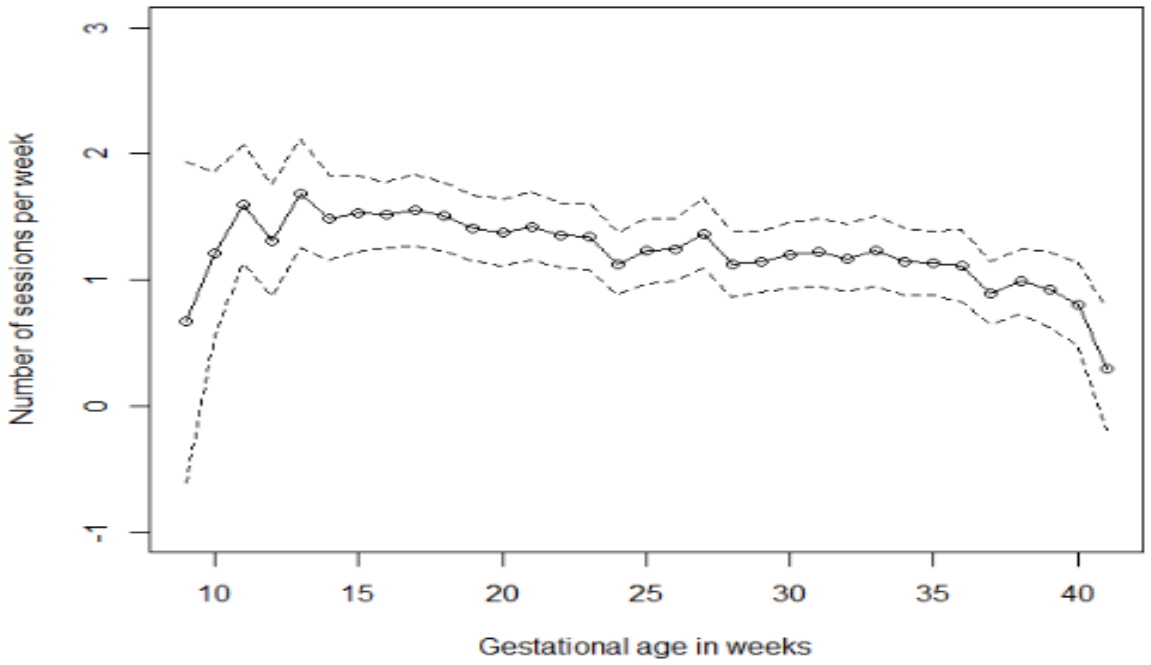

Figure 6. The average weekly number of EXE sessions attended during the entire study period.
All participants randomised to EXE are included. The attendance is registered from randomisation to delivery. Full line, mean number of sessions attended; Dotted lines, Confidence interval.

The women in EXE were affiliated to the intervention for approximately 23 weeks from randomisation to delivery or to the date of lost to follow-up or discontinuation. On average, the women in EXE joined 34 exercise sessions throughout the intervention period. The participation level varied from 0 to 80 sessions with a median of 35 sessions from randomisation to delivery. 40% of the women attended less than 1 session per week, 32% participated in 1-1.9 sessions per week and 28% participated in 2-3 sessions per week. Thus, 60% of the participants attended 1-3 sessions/week (Figure 7).

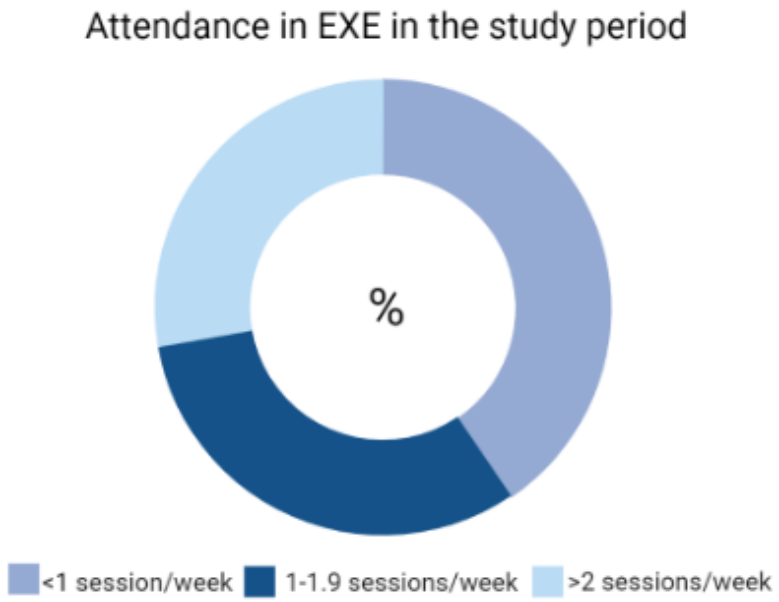

Figure 7. Attended EXE sessions in the entire study period
Attendance was registered from randomisation to delivery in the entire study period going from October 2018 to May 2021.

Motivational counselling on physical activity

Participants randomised to MOT joined approximately 5 of 7 counselling sessions during their pregnancy, corresponding to an adherence rate of 70% (Paper 2). The participation level ranged from 0 to 7 counselling sessions. 40% of the participants in MOT attended all seven sessions and 24% joined six sessions (Table 3).

	0	**1**	**2**	**3**	**4**	**5**	**6**	**7**
Sessions attended, n (%)	6 (7)	6 (7)	3 (3)	5 (6)	2 (2)	9 (10)	21 (24)	35 (40)

Table 3. Number and percentage of MOT sessions attended in the entire study period.
MOT, motivational counselling on physical activity.

Moderate-to-vigorous intensity physical activity assessed by the activity tracker

In brief, the main result from the activity tracker showed that pregnant women who were offered to participate in EXE increased their weekly MVPA significantly compared to pregnant women who were offered CON (Figure 1 and Table 2, Paper 2). Moderate-to-vigorous intensity PA was positively associated with the number of exercise sessions attended in EXE from randomisation to delivery (p=0.038). No difference was found on the weekly MVPA between participants in CON and MOT nor between EXE and MOT (Table 2, Paper 2), even though the proportion of completers were higher that needed to detect a statistical difference between the three groups. The effect evaluation showed

that the weekly MVPA in all three groups was lower than the stipulated effect size in the sample size calculation, but SD's were within the estimated range at 116 min/week (CON: 79 min/week, EXE: 110 min/week, MOT: 79 min/week).

Participants in all three groups maintained their MVPA from randomisation to delivery (Figure 1, top left plot, Paper 2), which contrasts with the considerable decline of PA previously reported during pregnancy[32]. MVPA during the entire pregnancy among participants in CON, EXE and MOT are shown in Figure 8.

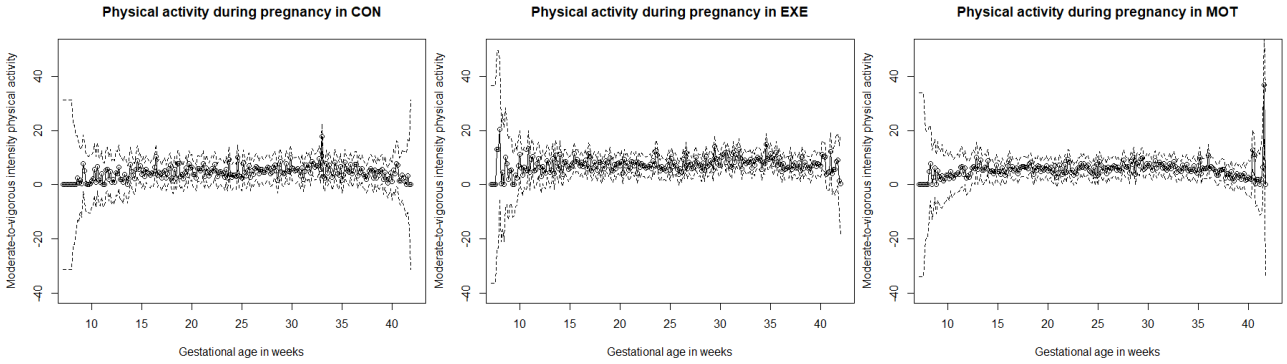

Figure 8. Physical activity at moderate-to-vigorous intensity during pregnancy.
Moderate-to-vigorous intensity physical activity during pregnancy (gestational age in weeks) in the three FitMum groups; CON, control group; EXE, structured supervised exercise training; MOT, motivational counselling on physical activity.

No previous studies obtained PA in pregnancy with a comparable PA tracker. However, few previous RCTs in pregnant women carried out interventions with components similar to EXE or MOT and assessed the PA level objectively at the same time (Table 2, orange sections). The effects of the interventions on PA were mixed; despite the similarities with the intervention design in EXE, Oostdam et al.[56] found no significant differences in MVPA between intervention and control groups measured with accelerometer. In contrast, Seneviratne et al.[59] found that the intervention group improved PA compared to controls measured with a cycle ergometer. Common to both studies was that the adherence to the intervention was low with 16% and 33%, respectively, of the participants in the intervention groups completing half of the prescribed sessions[56,59]. As in MOT, Currie et al.[65] found no differences in PA between the intervention with tailored face-to-face consultations and controls. In contrast to FitMum, MVPA declined during pregnancy among participants in both intervention and control groups in the study by Currie et al.[65].

Low compliance to the physical activity recommendations

Based on PA tracker measurements, less than 10% of the participants in EXE and MOT achieved the international and Danish recommendations of 150 min/week[1] and 210 min/week[4], respectively (calculations not shown). As presented in the background section of this present thesis, studies have shown a varying prevalence of PA during pregnancy; a cross sectional study[47] in which 1,279 women were included within 72 hours postpartum found that less than 8% of the women were physically active at a minimum of 150 min/week in each trimester. In contrast, half of the 3,868 pregnant women (47%) enrolled in a Swedish cross-sectional study from 2016[129] reported that they achieved the PA recommendation, and as already mentioned 38% of a pregnant Danish population of first-trimester pregnant women met the recommendation[26]. Notably, the prevalence in these studies were assessed subjectively and on women not enrolled in PA interventions.

Physical activity trackers as intervention facilitators

Beyond the PA trackers used as outcome measurement tools, PA trackers also can facilitate and motivate behavioural change per se. It is unknown how and how much participants in FitMum engaged with the tracker during the intervention period. All activity trackers were identically pre-set. After randomisation, women in MOT were supported to personalise the tracker with, e.g., individual goal settings and PA notifications. Participants in MOT used the tracker to a varying degree (unpublished data); some used the tracker as a watch or followed their steps and/or sleep patterns, while some turned on the PA and phone notifications. Participants in EXE were only instructed during the first attended EXE session in how to observe their heart rate to aim for a moderate intensity PA level. It is unknown how and to what degree EXE participants interacted with the tracker outside the sessions. Similarly, it is unknown to what extent participants in CON interacted with the activity tracker. Utilising a consumer-based wearable activity tracker as either the primary component of an intervention or as part of a broader PA intervention has the potential to improve MVPA, steps and energy expenditure among adults[130–132]. In the view of this, participants in CON may have increased their PA level without engaging in planned interventions. However, we assume that a potential PA improvement in CON would also apply for EXE and MOT. A limitation is, however, that the accumulated pregnancy PA may be elevated in all three groups due to the underlying motivation from simply wearing the tracker. This theory is difficult to verify because it is not possible to add a fourth group not intervening in interventions and not wearing the tracker if the tracker is used as the measurement tool. However, PA could be obtained by DLW[85–87] or PA recall questionnaires as an alternative to objective measurement[83,84].

Physical activity assessed by the doubly labelled water

Findings from DLW showed no differences between groups (Figure 8, Paper 2). The mean PA levels in the three groups were: CON: 1.3±0.1, EXE: 1.4±0.1, and MOT: 1.3±0.1. Compared to a study by Löf[113], the PA levels in FitMum were lower. Löf assessed the effect on energy expenditure caused by pregnancy induced changes in PA measured by DLW in 18 women in gestational week 32 and 21 non-pregnant women. The average PA level among pregnant women was significantly lower than the corresponding value for the non-pregnant controls (pregnant women: (mean ± SD) 1.6±0.1, non-pregnant women: 1.9±0.2, $p<0.001$). Even though Löf drew attention to the challenges of comparing physical activity level in pregnant and non-pregnant states, Löf suggested that the lower PA level in pregnancy compared to non-pregnant women might be because pregnant women in the third trimester choose slower activities.

Physical activity assessed by the Pregnancy Physical Activity Questionnaire

Physical activity domains

Participants in all three groups stated that their total PA (MET-h/week) was maintained from inclusion to the 29th gestational week but decreased from inclusion to the 35th gestational week (CON: $p=0.001$, EXE: $p=0.048$, MOT: $p<0.001$) (Table 4, Paper 2). In FitMum, PA at moderate intensity was maintained at the same level over the course of pregnancy in all three groups. As the only RCT listed in Table 2 (intervention similar to MOT), Hawkins et al.[64] assessed PA with PPAQ. They found that participants in the intervention group had a smaller decline in the total PA and MVPA compared to controls (total PA: -42.7 vs. -2.1, $p=0.02$, MVPA: -30.6 vs. -10, $p=0.05$).

Participants in MOT stated that they increased PA at vigorous intensity from inclusion to the 29th and 35th gestational week, respectively (visit 1: 1±2 MET-h/week, visit 2: 3±5 MET-h/week, visit 3: 2±5 MET-h/week, $p=0.002$ and $p=0.026$) (Table 4, Paper 2). The clinical importance of the vigorous-intensity findings must be considered as minimal due to the low change in MET-h/week.

Participants in both EXE and MOT stated themselves more engaged in sport activities over the course of pregnancy compared to inclusion (Table 4, Paper 2). Comparisons between the groups showed that participation in sport activities was higher among participants in EXE compared to CON and MOT at both the 29th and the 35th gestational week. Hawkins et al.[64] (Table 2) found that the intervention group similar to MOT had a greater increase in sport activities compared to controls.

Light-intensity activities accounted for the largest proportion of the total PA in all three groups over the course of pregnancy. Moderate-to-vigorous intensity PA accounted for a slightly larger proportion of the total PA in EXE than in CON and MOT, but overall, MVPA accounted for about one-fourth

of the total PA in all three groups (CON: visit 1: 21%, visit 2: 21%, visit 3: 21%; EXE: visit 1: 25%, visit 2: 28%, visit 3: 29%; MOT: visit 1: 23%, visit 2: 25%, visit 3: 24%, (Table 4, Paper 2) (specific calculations not shown).

Impact of the COVID-19 restrictions

From physical to online interventions

The FitMum study design was acutely converted into an online format when the COVID-19 restrictions made it impossible to continue the original physical setup. Most participants (55%) received the physical intervention only, and 29% received the online intervention only (Figure 9).

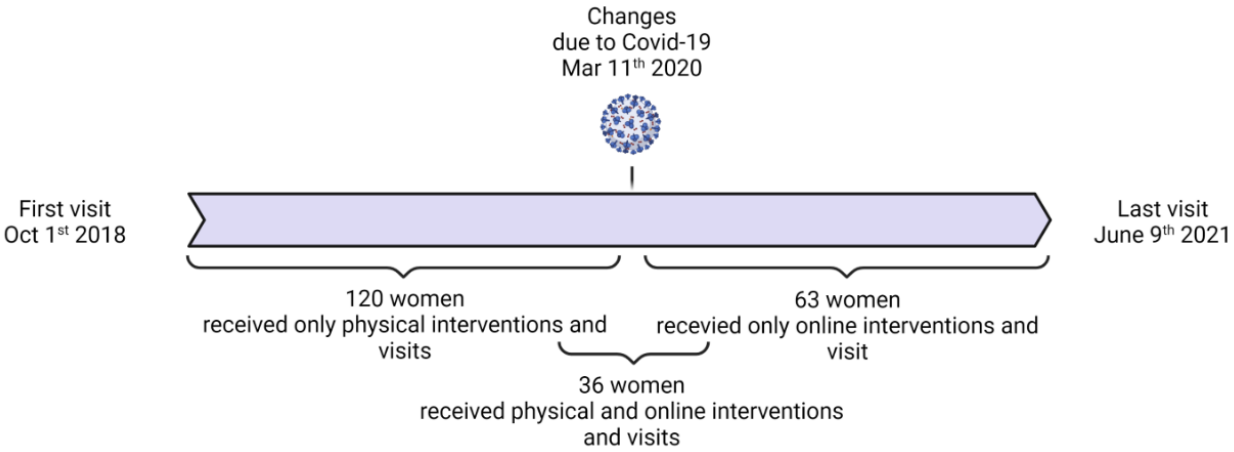

Figure 9. Timeline and distribution of participants in relation to COVID-19.

The adherence rate in EXE increased significantly to just above half of the recommended sessions/week during the online setup compared to the physical but still remained low (online: 1.6 [95% CI, 1.3;2.0] sessions/week, physical: 1.1 [0.9;1.4] sessions/week, p=0.027) (Figure 6, Paper 2). The distribution of attendance for participants who received the physical and the online version of EXE are illustrated in Figure 10.

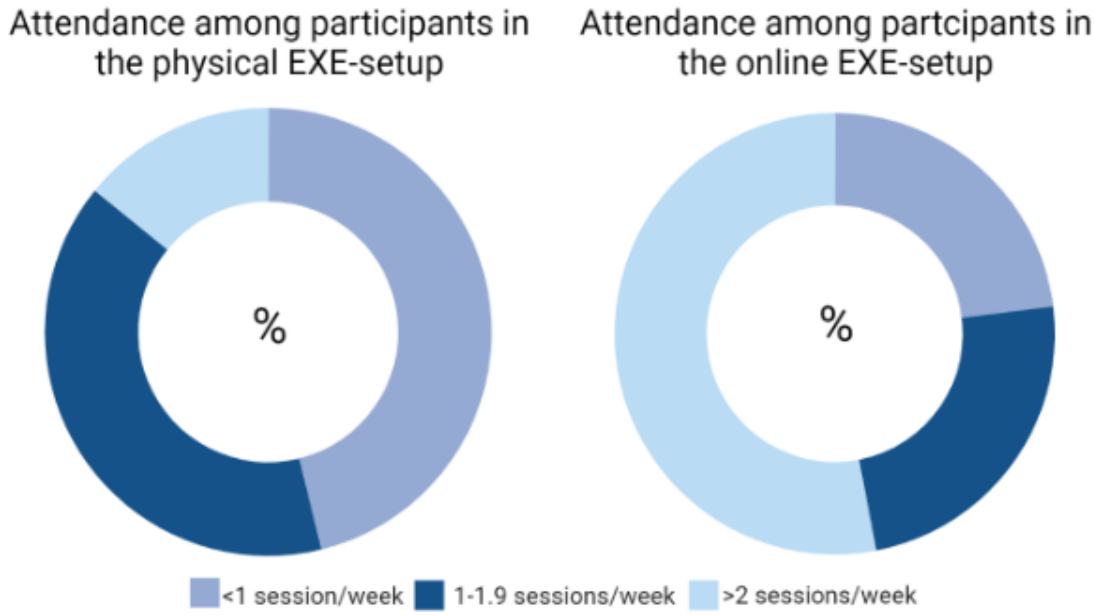

Figure 10. Attended sessions in the physical and online version of EXE.
Sessions are registered from randomisation to delivery among all participants randomised to EXE.

Moderate-to-vigorous intensity PA did not differ correspondingly (CON: -14 [-49;22] min/week, p=0.444, EXE: -16 [-42;11] min/week, p=0.251, MOT: -6 [-37;25] min/week, p=0.712) (Figure 6, Paper 2) despite the fact that MVPA was positively associated with the number of EXE sessions attended from randomisation to delivery in the original setup. The first part of the online EXE sessions was self-administrated, and it is unknown if and how the participants were physically active.

Semi-structured interviews of 24 pregnant women who participated in an online group exercise program during the COVID-19 restrictions[133], revealed that pregnant women felt safe during home-based exercise training. The women reported increased accessibility to be physically active and expressed that they had more time than before the restrictions to participate in exercise sessions.

COVID-19 reduced physical activity

Recently published studies from the UK and US show that COVID-19 restrictions imposed to reduce infection rates disrupted the everyday life of pregnant women; sedentary time was increased, and PA decreased due to fear of leaving the house and thus increasing the risk of being infected[134,135]. These findings are in line with the impact of COVID-19 on Danes' PA behaviour[136]; younger adults and adults (70 and 77% of those being women) experienced a decrease of 21 and 6%, respectively, in mean min of PA/week. It appears that during a pandemic like COVID-19 it is even more difficult to comply with national PA guidelines than it was before the restrictions. Converting the FitMum

interventions into online delivery did not affect MVPA, but it did increase the attendance in EXE. It might be assumed that the home-based exercise training was less time-consuming since commuting was not necessary. A result of this could be higher attractiveness and flexibility as the process evaluation of the DALI trial[81] suggested.

Paper 3: Reach, fidelity, dose and mechanisms of impact of the structured supervised exercise training and motivational counselling on physical activity

The last part of this section will present the main results of Paper 3 and place them in a discussion with the context of international state-of-the-art research within the area of PA in pregnancy.

Reach

The majority (78%) of the included participants in FitMum were introduced to the study in connection with either booking or attending their first-trimester ultrasonic scan. Participants included were a selected group of women with interest in contributing to research and a general interest in their own and their child's health. Participants in both intervention groups reported a high degree of autonomy in planning their work and everyday life including PA, which gave them an advantage in participating in the interventions. These findings correspond to the assumptions of selection bias presented in the section of 'Participant representativeness'. It must be considered that attendance and PA might have been lower among participants with lower socio-economic status.

Dose and fidelity

Both interventions were delivered with a high degree of fidelity before and during the COVID-19 onset. Participants in EXE found it difficult to reconcile the intervention with everyday life; they expressed that the intervention accessibility was high, but to attend sessions the women were dependent on social support and high working-time autonomy. In the light of the recently proposed new classifications for absolute and relative contraindications of engaging in prenatal PA[128], Moholdt and Hawley spoke of a possible new trend when they suggested that pregnant women could exercise at vigorous intensity[101]. Moholdt and Hawley argued that PA at vigorous intensity would be time-intense and time-efficient, which is in line with the fact that lack of time is one of the most common barriers to PA participation among pregnant women[137–139]. Including vigorous intensity PA could potentially increase the PA adherence in pregnant women. A meta-analysis of eight cohort studies (n=7,225) and five RCTs (n=623) on pregnant women performing prenatal vigorous intensity PA indicated that vigorous intensity PA completed into the third trimester appeared to be safe for most healthy pregnancies[140]. The current Danish PA recommendations advise against vigorous intensity

PA in pregnancy if the pregnant women are not used to exercise at this intensity. Pregnant women habitually engaging in vigorous intensity PA can continue. However, they are advised against exhausting activities such as long distance running[4], which is supported by the World Health Organisation and ACOG[1,2]. Noteworthy is that healthy pregnant women in Australia recently have been recommended to exercise at vigorous intensity[141,142]. This could point to more offensive recommendations on prenatal PA in the future offering more PA for more women.

Shorter but more frequent exercise sessions

As previously mentioned, the design of EXE was inspired by a RCT by Wang et al[60]. They reported a relatively high attendance rate where 90% of the participants attended more than 80% of the program. The intervention periods in Wang et al. and FitMum were almost equal (26-27 weeks) but the total number (mean ± SD) of exercise sessions attended in Wang et al. was 73±10 ranging from 60 to 130 sessions in the intervention period, which is more than twice as many sessions attended in EXE (mean 34, 95% CI, 29;39). One explanation could be that the duration of the sessions (35±6 min) was lower in the study of Wang et al. compared to the one-hour sessions in EXE. It might be assumed that lower duration and higher frequency of the exercise sessions would be the most efficient way to increase PA. As previously mentioned, Seneviratne et al.[59] found low adherence to the intervention but increased PA by implementing a design with shorter but more frequent sessions. However, it must be taken into consideration that some participants could feel that they did not 'gain enough' due to the lower duration but the same transportation time. In contrast to the study by Wang et al.[60], no lower limit of adherence to the interventions was predefined in FitMum, and participants, regardless of participation level, were included in the analyses. If participants in EXE were asked to attend no less than three sessions/week as in Wang et al., the adherence rate could have been increased. However, a strict adherence limit could have also increased the overall dropout rate in the study.

A detailed distribution of the attendance in MOT is shown in Figure 11. It shows that 40% of participants in MOT attended all seven counselling sessions (left figure). The distribution of group and individual sessions differ among participants randomised to MOT (n=87) and participants still included in MOT (those who are not lost to follow-up). Among participants still included, the individual sessions are the most attractive (right figure). Of the 87 participants randomised to MOT, 85% (n=84) were still included at group session 1 (G1), 93% (n=81) at individual session 1 (I1), 92%

(n=80) at individual session 2 (I2), 87% (n=76) at individual session 3 (I3), 87% (n=76) at group session 2 (G2), 84% (n=73) at individual session 4 (I4) and 82% (n=71) at group session 3 (G3).

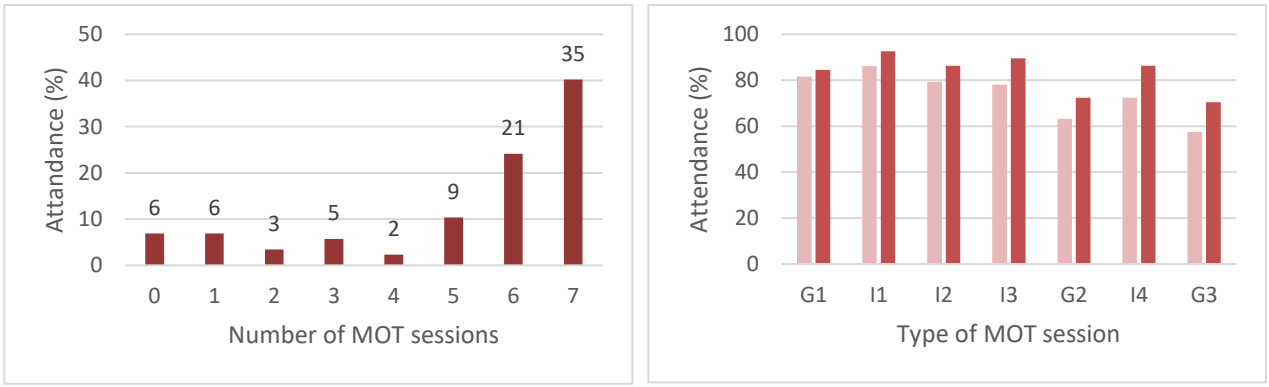

Figure 11. Attendance in motivational counselling on physical activity.
Left figure: Number and percentage of attended MOT sessions. Right figure: Type of MOT session attended. Light red: Participants randomised to MOT. Dark red: Participants randomised to MOT and still included (not lost to follow-up). G, Group counselling sessions; I, Individual counselling sessions; MOT, motivational counselling on physical activity.

Mechanisms of impact

Participants in EXE and MOT expressed opposing mechanisms of impact (Paper 3). The structured sessions in EXE represented a commitment to others and resulted in participants in EXE not having to 'renegotiate' to prioritise PA. Further, participants in EXE expressed that social support had a decisive impact on their participation as they became dependent on practical support from their partners. As in the process evaluation of the DALI study[81], it was revealed that especially participation in the EXE intervention was very time-consuming for the participants and that participation affects everyday life including time spend with family (Paper 3). Participants in EXE felt an increased confidence when PA was supervised by competent health professionals, whereas participants in MOT perceived a themselves empowered towards PA as they planned the PA with health professionals but performed the activity on their own. Support from health professionals was appreciated among participants in both EXE and MOT as some felt insecure with being physically active on their own or without guidance because they were nervous about exercising incorrectly. Individual adaptations towards the PA had a significant impact on women's desire and ability to participate in PA despite the experienced barriers of physical discomforts. As in the process evaluation of UPBEAT[80], the findings from the process evaluation of FitMum (Paper 3) argued for designing PA interventions with some degree of tailoring to strengthen intervention adherence. Even though the process evaluation of

UPBEAT[80] did not include the dimension of 'mechanisms of impact', they added a recommendation that a 'one size fits all' approach may not be effective, and emphasized that flexibility is key to retention.

Perceptions of PA were opposing in EXE and MOT which affected their engagement in PA. Participants in EXE perceived PA as limited to a certain timeslot and environmental-dependent as they attended a session, performed the PA, and then returned to home. They did not consider other types of activities in the overall impression of their PA level. In contrast, participants in MOT were more likely to integrate PA in their everyday life activities, example via active commuting, and recognised activities with lower intensity such as walking with the stroller, daily chores, and family activities as sufficient PA, however with less focus on intensity. The participants in MOT perceived themselves more active than objectively measured, which might be explained by the fact that they were made intensively aware of their PA at counselling sessions and by the SMS they received every week.

Conclusions

The main aim of this PhD thesis was to investigate how healthy, inactive pregnant women could implement PA in everyday life by offering them CON, EXE, or MOT (Paper 1 and 2). Moreover, the thesis aimed to explain the reach, fidelity and dose of two PA interventions and to understand the mechanisms of impact in relation to their effect (Paper 3).

Results from the wrist-worn PA tracker (Paper 2) showed that women offered EXE were more physically active at moderate-to-vigorous intensity throughout the pregnancy than those offered CON. However, no difference was found in MVPA between women offered CON or MOT nor between EXE or MOT. MVPA was maintained at the same level during the entire pregnancy in all three groups, and MVPA was positively associated with the number of exercise sessions attended. However, participants in EXE attended less than half of the recommended sessions. Interestingly, participants who received the online EXE intervention due to COVID-19 restrictions joined more exercise sessions compared to those who received the physical intervention only. However, MVPA did not differ between participants who received the physical or the online intervention. Neither DLW assessed at the 29th week of gestation nor PPAQ-DK (the total PA component) assessed at the 29th and 35th weeks of gestation showed any PA differences between the three groups. However, participants in MOT indicated in PPAQ-DK that they increased the level of vigorous intensity PA at the 29th and 35th weeks of gestation compared to at inclusion.

Findings from the mixed methods process evaluation of the two PA interventions (Paper 3) revealed that participants included in the FitMum study was a selected group of educated pregnant women. They had a high everyday life autonomy by which they could structure and organise their working life with large flexibility. These practical and contextual factors interacted more than anticipated with participation in especially EXE and are considered as important to consider in PA interventions during pregnancy. EXE and MOT were well delivered with high fidelity during the FitMum study. Although the interventions were altered into online setup due to the COVID-19 restrictions the interventions were still well delivered with high fidelity. The dose received in EXE was low which might be explained by the fact that participation in EXE affected the everyday life including time spend with family. Participants in EXE and MOT perceived a conflict between spending time on PA and family obligations. The dose received increased in the online setup which might be explained by the fact that the everyday lives of the participants were organised differently during the COVID-19 restrictions. In general, it was revealed that participation in EXE was mainly feasible for women with high working-time autonomy even though the intervention accessibility was high.

Mechanisms of impact comprised of a perception of commitment to the intervention among participants in EXE, whereas a perception of empowerment and autonomy towards PA was essential among participants in MOT. The perception of PA was different in the two intervention groups as participants in EXE perceived PA as the EXE sessions only. They considered PA as activities only with a certain level of intensity and focused particularly on bodily capacities, changes and appearance that PA brought. In contrast, participants in MOT had a wider perception of PA and recognised all daily activities, including activities with lower intensity, as sufficient PA. Participants in MOT preferred that PA did not limit their presence in family matters and often scheduled PA as active commuting or including family in the PA performance. Participants in MOT perceived themselves more vigorously active than what was objectively measured (Paper 2), which might be caused by the intense PA attention in the MOT intervention (Paper 3). Findings from the process evaluation of the two PA interventions in FitMum supported a complexity in PA and the interacting components by which pregnant women are affected. To optimise the effectiveness of interventions addressing PA in pregnancy, barriers to intervention attendance and the perceptions of commitment, PA empowerment and PA perceptions need to be addressed. It does not appear that one single strategy or component is able to increase PA sufficiently.

Perspectives for the future

Based on the most effective intervention on PA during pregnancy (EXE) presented in Paper 2, the explanatory findings of reach, fidelity, dose and mechanisms of impact in Paper 3, and the international state-of-the-art research within the area of PA in pregnancy, a combination of physical attendance and home-based, online exercise sessions might be beneficial intervention to increase the attendance rate and the PA among pregnant women. The total time spent on PA and the practicalities of PA will be less, and the flexibility and accessibility of the intervention will be greater.

Currently, the FitMum participants' 1-year postpartum PA are continuously assessed by the wrist-worn PA tracker. Data will reveal the sustainability of PA and add knowledge to the comprehensive insight obtained in FitMum into PA in pregnancy. Moreover, data on PA self-efficacy (obtained by Pregnancy Exercise Self-efficacy Scale, P-ESES), PA behavioural regulation (obtained by the Behavioural Regulation In Exercise Questionnaire, BREQ) and quality of life (obtained by the 36-Item Short Form Health Survey, SF-36) will uncover further dimensions of the FitMum interventions.

References

1. Bull FC, Al-Ansari SS, Biddle S, et al. World Health Organization 2020 guidelines on physical activity and sedentary behaviour. *British Journal of Sports Medicine*. 2020;54(24):1451-1462.
2. The American College of Obstetricians and Gynecologists. Physical Activity and Exercise During Pregnancy and the Postpartum Period. ACOG Committee Opinion No. 804. *Obstetrics and Gynecology*. 2020;135:e178-88.
3. Mottola MF, Davenport MH, Ruchat SM, et al. 2019 Canadian guideline for physical activity throughout pregnancy. *British Journal of Sports Medicine*. 2018;52(21):1339-1346.
4. The Danish Health Authorities. Recommendations for pregnant women. https://www.sst.dk/da/viden/fysisk-aktivitet/anbefalinger-om-fysisk-aktivitet/gravide. Published 2021.
5. Guthold R, Stevens GA, Riley LM, Bull FC. Worldwide trends in insufficient physical activity from 2001 to 2016: a pooled analysis of 358 population-based surveys with 1·9 million participants. *The Lancet Global Health*. 2018;(18):1-10.
6. Richardsen KR, Falk RS, Jenum AK, et al. Predicting who fails to meet the physical activity guideline in pregnancy: A prospective study of objectively recorded physical activity in a population-based multi-ethnic cohort. *BMC Pregnancy and Childbirth*. 2016;16(186):1-11.
7. Santo EC, Forbes PW, Oken E, Belfort MB. Determinants of physical activity frequency and provider advice during pregnancy. *BMC Pregnancy & Childbirth*. 2017;17(286):1-11.
8. Lindqvist M, Mogren I, Eurenius E, Edvardsson K, Persson M. "An on-going individual adjustment": a qualitative study of midwives' experiences counselling pregnant women on physical activity in Sweden. doi:10.1186/1471-2393-14-343
9. Fair F, Soltani H. A meta-review of systematic reviews of lifestyle interventions for reducing gestational weight gain in women with overweight or obesity. *Obesity Reviews*. 2021:1-21.
10. Ruchat SM, Mottola MF, Skow RJ, et al. Effectiveness of exercise interventions in the prevention of excessive gestational weight gain and postpartum weight retention: A systematic review and meta-analysis. *British Journal of Sports Medicine*. 2018;52(21):1347-1356.
11. Díaz-Burrueco JR, Cano-Ibáñez N, Martín-Peláez S, Khan KS, Amezcua-Prieto C. Effects on the maternal-fetal health outcomes of various physical activity types in healthy pregnant women. A systematic review and meta-analysis. *European Journal of Obstetrics &*

Gynecology and Reproductive Biology. 2021;262:203-215.

12. Wang J, Wen D, Liu X, Liu Y. Impact of exercise on maternal gestational weight gain. An updated meta-analysis of randomized controlled trials. *Medicine*. 2019;98(27):1-10.
13. Hayes L, McParlin C, Azevedo L, et al. The Effectiveness of Smoking Cessation, Alcohol Reduction, Diet and Physical Activity Interventions in Improving Maternal and Infant Health Outcomes: A Systematic Review of Meta-Analyses. *Nutrients*. 2021;13(1036):1-31.
14. Bhattacharjee J, Mohammad S, Adamo KB. Does exercise during pregnancy impact organs or structures of the maternal-fetal interface? *Tissue and Cell*. 2021;72:1-14.
15. Morales-Suárez-Varela M, Clemente-Bosch E, Peraita-Costa I, Llopis-Morales A, Martínez I, Llopis-González A. Maternal Physical Activity During Pregnancy and the Effect on the Mother and Newborn: A Systematic Review. *Journal of Physical Activity and Health*. 2020:1-18.
16. Sánchez-Polán M, Franco E, Silva-José C, et al. Exercise During Pregnancy and Prenatal Depression: A Systematic Review and Meta-Analysis. *Frontiers in physiology*. 2021;12:1-13.
17. Navas A, Carrascosa M del C, Artigues C, et al. Effectiveness of Moderate-Intensity Aerobic Water Exercise during Pregnancy on Quality of Life and Postpartum Depression: A Multi-Center, Randomized Controlled Trial. *Journal of Clinical Medicine*. 2021;10(11):2432.
18. Nakamura A, Van Der Waerden J, Melchior M, Bolze C, El-Khoury F, Pryor L. Physical activity during pregnancy and postpartum depression: Systematic review and meta-analysis. *Journal of Affective Disorders*. 2019;246:29-41.
19. Davenport MH, McCurdy AP, Mottola MF, et al. Impact of prenatal exercise on both prenatal and postnatal anxiety and depressive symptoms: A systematic review and meta-analysis. *British Journal of Sports Medicine*. 2018;52(21):1376-1385.
20. Liu N, Gou W, Wang J, et al. Effects of exercise on pregnant women's quality of life: A systematic review. *European Journal of Obstetrics and Gynecology and Reproductive Biology*. 2019;242:170-177. doi:10.1016/J.EJOGRB.2019.03.009
21. Davenport MH, Kathol AJ, Mottola MF, et al. Prenatal exercise is not associated with fetal mortality: A systematic review and meta-analysis. *British Journal of Sports Medicine*. 2019;53(2):108-115.
22. Davenport MH, Meah VL, Ruchat SM, et al. Impact of prenatal exercise on neonatal and childhood outcomes: A systematic review and meta-analysis. *British Journal of Sports*

Medicine. 2018;52(21):1386-1396.

23. Davenport MH, Yoo C, Mottola MF, et al. Effects of prenatal exercise on incidence of congenital anomalies and hyperthermia: A systematic review and meta-analysis. *British Journal of Sports Medicine*. 2019;53(2):116-123.
24. Beetham KS, Giles C, Noetel M, Clifton V, Jones JC, Naughton G. The effects of vigorous intensity exercise in the third trimester of pregnancy: A systematic review and meta-analysis. *BMC Pregnancy and Childbirth*. 2019;19(1):1-18.
25. Kramer MS, McDonald SW. Aerobic exercise for women during pregnancy. *Cochrane Database of Systematic Reviews*. 2009;2006(4). doi:10.1002/14651858.CD000180.pub2
26. Broberg L, Ersbøll AS, Backhausen MG, Damm P, Tabor A, Hegaard HK. Compliance with national recommendations for exercise during early pregnancy in a Danish cohort. *BMC Pregnancy and Childbirth*. 2015;15(1). doi:10.1186/s12884-015-0756-0
27. Ussery EN, Hyde ET, Bombard JM, Juhl AL, Kim SY, Carlson SA. Physical Activity Before and During Pregnancy, Colorado Pregnancy Risk Assessment Monitoring System, 2012–2015. *Preventing Chronic Disease*. 2020;17(17). doi:10.5888/PCD17.190366
28. Fioretti E, Fioretti E, Palandri L, et al. Physical activity during pregnancy in Italy: prevalence, intensity and associated factors. *European Journal of Public Health*. 2020;30(Supplement_5). doi:10.1093/EURPUB/CKAA166.989
29. Harrison AL, Taylor NF, Shields N, Frawley HC. Attitudes, barriers and enablers to physical activity in pregnant women: a systematic review. *Journal of Physiotherapy*. 2018;64(1):24-32. doi:10.1016/j.jphys.2017.11.012
30. Carlsen OCL, Gudmundsdóttir HK, Bains KES, et al. Physical activity in pregnancy: a Norwegian-Swedish mother-child birth cohort study. *AJOG Global Reports*. 2021;1(1):100002. doi:10.1016/J.XAGR.2020.100002
31. Okafor UB, Goon D Ter. Physical activity and exercise during pregnancy in Africa: a review of the literature. *BMC Pregnancy and Childbirth 2020 20:1*. 2020;20(1):1-17. doi:10.1186/S12884-020-03439-0
32. Currie S, Sinclair M, Murphy MH, Madden E, Dunwoody L, Liddle D. Reducing the Decline in Physical Activity during Pregnancy: A Systematic Review of Behaviour Change Interventions. *PLoS ONE*. 2013;8(6):1-12. doi:10.1371/journal.pone.0066385
33. Gaston A, Cramp A. Exercise during pregnancy: A review of patterns and determinants. *Journal of Science and Medicine in Sport*. 2011;14:299-305.

doi:10.1016/j.jsams.2011.02.006

34. Bacchi E, Bonin C, Zanolin ME, et al. Physical activity patterns in normal-weight and overweight/obese pregnant women. *PLoS ONE*. 2016;11(11):1-11.
35. Borg GAV. Psychophysical bases of perceived exertion. 1982.
36. Downs DS, Chasan-Taber L, Evenson KR, Leiferman J, Yeo S. Physical activity and pregnancy: past and present evidence and future recommendations. *Research quarterly for exercise and sport*. 2012;83(4):485-502. doi:10.1080/02701367.2012.10599138
37. Evenson KR, Hesketh KR. Monitoring Physical Activity Intensity During Pregnancy. *American Journal of Lifestyle Medicine*. 2021. doi:10.1177/15598276211052277
38. Evenson KR, Wen F. National trends in self-reported physical activity and sedentary behaviors among pregnant women: NHANES 1999-2006. *Preventive Medicine*. 2010;50(3):123-128. doi:10.1016/J.YPMED.2009.12.015
39. Broberg L, Ersbøll AS, Backhausen MG, Damm P, Tabor A, Hegaard HK. Compliance with national recommendations for exercise during early pregnancy in a Danish cohort. *BMC pregnancy and childbirth*. 2015;15:317. doi:10.1186/s12884-015-0756-0
40. Owe KM, Nystad W, Bø K. Correlates of regular exercise during pregnancy: The Norwegian Mother and Child Cohort Study. *Scandinavian Journal of Medicine and Science in Sports*. 2009;19(5):637-645. doi:10.1111/j.1600-0838.2008.00840.x
41. Juhl M, Madsen M, Andersen AMN, Andersen PK, Olsen J. Distribution and predictors of exercise habits among pregnant women in the Danish National Birth Cohort. *Scandinavian Journal of Medicine & Science in Sports*. 2012;22(1):128-138. doi:10.1111/J.1600-0838.2010.01125.X
42. Coll CVN, Domingues MR, Gonçalves H, Bertoldi AD. Perceived barriers to leisure-time physical activity during pregnancy: A literature review of quantitative and qualitative evidence. *Journal of Science and Medicine in Sport*. 2017;20(1):17-25. doi:10.1016/j.jsams.2016.06.007
43. Koleilat M, Vargas N, Vantwist V, Damianova Kodjebacheva G. Perceived barriers to and suggested interventions for physical activity during pregnancy among participants of the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) in Southern California. *BMC Pregnancy & Childbirth*. 2021;21(69):1-9.
44. Hegaard HK, Damm P, Hedegaard M, et al. Sports and leisure time physical activity during pregnancy in nulliparous women. *Maternal and Child Health Journal*. 2011;15(6):806-813.

doi:10.1007/s10995-010-0647-y

45. Catov JM, Parker CB, Gibbs BB, et al. Patterns of leisure-time physical activity across pregnancy and adverse pregnancy outcomes. *International Journal of Behavioral Nutrition and Physical Activity*. 2018;15(1):1-10. doi:10.1186/s12966-018-0701-5
46. Borodulin K, Evenson KR, Herring AH. Physical activity patterns during pregnancy through postpartum. *BMC Women's Health*. 2009;9(1):32. doi:10.1186/1472-6874-9-32
47. Nascimento SL, Surita FG, Godoy AC, Kasawara KT, Morais SS. Physical activity patterns and factors related to exercise during pregnancy: A cross sectional study. *PLoS ONE*. 2015;10(6):1-14. doi:10.1371/journal.pone.0128953
48. Walasik I, Szymusik I, Kwiatkowska K, Kaczyńska KK. Physical activity patterns among 9000 pregnant women in poland: A cross-sectional study. *International Journal of Environmental Research and Public Health*. 2020;17(5):1-12.
49. Williams SL, French DP. What are the most effective intervention techniques for changing physical activity self-efficacy and physical activity behaviour - And are they the same? *Health Education Research*. 2011;26(2):308-322. doi:10.1093/her/cyr005
50. James P, Morgant R, Merviel P, et al. How to promote physical activity during pregnancy : A systematic review. *Journal of Gynecology Obstetrics and Human Reproduction*. 2020;49(9).
51. Craike M, Hill B, Gaskin CJ, Skouteris H. Interventions to improve physical activity during pregnancy: a systematic review on issues of internal and external validity using the RE-AIM framework. *BJOG: An International Journal of Obstetrics and Gynaecology*. 2017;124(4):573-583. doi:10.1111/1471-0528.14276
52. Oude Rengerink K, Logtenberg S, Hooft L, Bossuyt PM, Mol BW. Pregnant womens' concerns when invited to a randomized trial: A qualitative case control study. *BMC Pregnancy and Childbirth*. 2015;15(1). doi:10.1186/s12884-015-0641-x
53. Kenyon S, Dixon-Woods M, Jackson CJ, Windridge K, Pitchforth E. Participating in a trial in a critical situation: a qualitative study in pregnancy. *Quality & Safety in Health Care*. 2006;15(2):98. doi:10.1136/QSHC.2005.015636
54. van der Zande ISE, van der Graaf R, Hooft L, van Delden JJM. Facilitators and barriers to pregnant women's participation in research: A systematic review. *Women and Birth*. 2018;31(5):350-361. doi:10.1016/j.wombi.2017.12.009
55. Walter JK, Davis MM. Who's Willing? Characteristics Associated with Willingness to Participate in Clinical Research. *Choice Reviews Online*. 2016;43(12).

doi:10.5860/choice.43sup-0356

56. Oostdam N, Van Poppel MNM, Wouters MGAJ, et al. No effect of the FitFor2 exercise programme on blood glucose, insulin sensitivity, and birthweight in pregnant women who were overweight and at risk for gestational diabetes: Results of a randomised controlled trial. *BJOG: An International Journal of Obstetrics and Gynaecology*. 2012;119(9):1098-1107.
57. Leung Hui A, Back L, Ludwig S, et al. Effects of lifestyle intervention on dietary intake, physical activity level, and gestational weight gain in pregnant women with different pre-pregnancy Body Mass Index in a randomized control trial. *BMC Pregnancy and Childbirth*. 2014;14(331):1-9.
58. Poston L, Bell R, Croker H, et al. Effect of a behavioural intervention in obese pregnant women (the UPBEAT study): a multicentre, randomised controlled trial. *The Lancet Diabetes & Endocrinology*. 2015;3(10):767-777.
59. Seneviratne S, Jiang Y, Derraik J, et al. Effects of antenatal exercise in overweight and obese pregnant women on maternal and perinatal outcomes: a randomised controlled trial. *BJOG: An International Journal of Obstetrics & Gynaecology*. 2016;123(4):588-597.
60. Wang C, Wei Y, Zhang X, et al. A randomized clinical trial of exercise during pregnancy to prevent gestational diabetes mellitus and improve pregnancy outcome in overweight and obese pregnant women. *American Journal of Obstetrics and Gynecology*. 2017;216(4):340-351.
61. Gaston A, Prapavessis H. Using a combined protection motivation theory and health action process approach intervention to promote exercise during pregnancy. *Journal of Behavioral Medicine*. 2014;37(2):173-184. doi:10.1007/s10865-012-9477-2
62. Aittasalo M, Raitanen J, Kinnunen TI, Ojala K, Kolu P, Luoto R. Is intensive counseling in maternity care feasible and effective in promoting physical activity among women at risk for gestational diabetes? Secondary analysis of a cluster randomized NELLI study in Finland. *International Journal of Behavioral Nutrition and Physical Activity 2012 9:1*. 2012;9(1):1-12. doi:10.1186/1479-5868-9-104
63. Renault KM, Nørgaard K, Nilas L, et al. The Treatment of Obese Pregnant Women (TOP) study: A randomized controlled trial of the effect of physical activity intervention assessed by pedometer with or without dietary intervention in obese pregnant women. *American Journal of Obstetrics and Gynecology*. 2014;210:134.e1-9.
64. Hawkins M, Chasan-Taber L, Marcus B, et al. Impact of an exercise intervention on physical

activity during pregnancy: The behaviors affecting baby and you study. *American Journal of Public Health*. 2014;104(10):e74-e81. doi:10.2105/AJPH.2014.302072

65. Currie S, Sinclair M, Liddle DS, Nevill A, Murphy MH. Application of objective physical activity measurement in an antenatal physical activity consultation intervention: a randomised controlled trial. *BMC Public Health*. 2015;15(1):1259. doi:10.1186/s12889-015-2548-x
66. Hayman M, Reaburn P, Browne M, Vandelanotte C, Alley S, Short CE. Feasibility , acceptability and efficacy of a web-based computer-tailored physical activity intervention for pregnant women - the Fit4Two randomised controlled trial. 2017:1-10. doi:10.1186/s12884-017-1277-9
67. Garber CE, Blissmer B, Deschenes MR, et al. Quantity and quality of exercise for developing and maintaining cardiorespiratory, musculoskeletal, and neuromotor fitness in apparently healthy adults: Guidance for prescribing exercise. *Medicine and Science in Sports and Exercise*. 2011;43(7):1334-1359. doi:10.1249/MSS.0b013e318213fefb
68. Moore G, Audrey S, Barker M, et al. Process evaluation in complex public health intervention studies: the need for guidance. *Journal of epidemiology and community health*. 2014;68(2):101-102. doi:10.1136/jech-2013-202869
69. Forman J, Heisler M, Damschroder LJ, Kaselitz E, Kerr EA. Development and application of the RE-AIM QuEST mixed methods framework for program evaluation. *Preventive medicine reports*. 2017;6:322-328. doi:10.1016/j.pmedr.2017.04.002
70. Moore G, Audrey S, Barker M, et al. Process evaluation of complex interventions: A summary of Medical Research Council guidance. In: *Complex Interventions in Health: An Overview of Research Methods*. ; 2015:222-231.
71. Skivington K, Matthews L, Simpson SA, et al. Framework for the development and evaluation of complex interventions: gap analysis, workshop and consultation-informed update. *Health technology assessment (Winchester, England)*. 2021;25(57):1-132. doi:10.3310/hta25570
72. Astbury B, Leeuw FL. Unpacking Black Boxes: Mechanisms and Theory Building in Evaluation. *American Journal of Evaluation*. 2010;31(3):363-381. doi:10.1177/1098214010371972
73. Skivington K, Matthews L, Simpson SA, et al. A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. *The BMJ*.

2021;374. doi:10.1136/BMJ.N2061

74. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. *The BMJ*. 2008;337(a1655):1-6. doi:10.1136/bmj.a1655
75. Moore G et al. Process evaluation of complex interventions: Medical Research Council guidance. 2015. doi:10.1136/bmj.h1258
76. Steckler, A.; Linnan L. Process evaluation for public health interventions and research. *Health Promotion Practice*. 2002;27(1):1-3.
77. Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: The RE-AIM framework. *American Journal of Public Health*. 1999;89(9):1322-1327. doi:10.2105/AJPH.89.9.1322
78. Holtrop JS, Rabin BA, Glasgow RE. Qualitative approaches to use of the RE-AIM framework: rationale and methods. *BMC Health Services Research*. 2018;18(1):177. doi:10.1186/s12913-018-2938-8
79. Harden SM, Gaglio B, Shoup JA, et al. Fidelity to and comparative results across behavioral interventions evaluated through the RE-AIM framework: a systematic review. *Systematic reviews*. 2015;4:155. doi:10.1186/s13643-015-0141-0
80. Poston L, Briley AL, Barr S, et al. Developing a complex intervention for diet and activity behaviour change in obese pregnant women (the UPBEAT trial); assessment of behavioural change and process evaluation in a pilot randomised controlled trial. *BMC pregnancy and childbirth*. 2013;13(1):148. doi:10.1186/1471-2393-13-148
81. Jelsma JGM, Simmons D, Gobat N, et al. Is a motivational interviewing based lifestyle intervention for obese pregnant women across Europe implemented as planned? Process evaluation of the DALI study. *BMC Pregnancy and Childbirth*. 2017;17(1):293. doi:10.1186/s12884-017-1471-9
82. Simmons D, van Poppel MNM. UPBEAT, RADIEL, and DALI: What's the difference? *The Lancet Diabetes and Endocrinology*. 2015;3(10):761. doi:10.1016/S2213-8587(15)00318-6
83. Chasan-Taber L, Schmidt MD, Roberts DE, Hosmer D, Markenson G, Freedson PS. Development and validation of a pregnancy physical activity questionnaire. *Medicine and Science in Sports and Exercise*. 2004;36(10):1750-1760. doi:10.1249/01.MSS.0000142303.49306.0D
84. Krøner FH, Knudsen S de P, Roland CB, Alomairah SA, Molsted S. Validity and reliability

of the Danish version of the pregnancy physical activity questionnaire to assess levels of physical activity during pregnancy. *Journal of Maternal-Fetal and Neonatal Medicine*. 2020. doi:10.1080/14767058.2020.1856807

85. Wong WW, Roberts SB, Racette SB, et al. The Doubly Labeled Water Method Produces Highly Reproducible Longitudinal Results in Nutrition Studies. *Journal of Nutrition*. 2014;144:777-783. doi:10.3945/jn.113.187823.reproducibility
86. Santini C, Dos T, Imakawa S, Dantas Moisés EC. Physical Activity during Pregnancy: Recommendations and Assessment Tools. *Rev Bras Ginecol Obstet*. 2017;39:424-432. doi:10.1055/s-0037-1604180
87. Abeysekera M V, Morris JA, O 'sullivan AJ. Techniques to measure free-living energy expenditure during pregnancy – A guide for clinicians and researchers. *Obstetric Medicine*. 2014;7(2):60-65. doi:10.1177/1753495X14528324
88. Rogers PJ. Using programme theory to evaluate complicated and complex aspects of interventions. *Evaluation*. 2008;14(1):29-48. doi:10.1177/1356389007084674
89. Roland CB, Knudsen S de P, Alomairah SA, et al. Structured supervised exercise training or motivational counselling during pregnancy on physical activity level and health of mother and offspring: FitMum study protocol. *BMJ Open*. 2021;11(3):1-11.
90. O'Connor PJ, Poudevigne MS, Cress ME, Motl RW, Clapp JF. Safety and efficacy of supervised strength training adopted in pregnancy. *Journal of Physical Activity and Health*. 2011;8(3):309-320. doi:10.1123/jpah.8.3.309
91. Gigtforeningen. https://www.gigtforeningen.dk/aquapunkt/aquamama/.
92. Andersen LK, Backhausen M, Hegaard HK, Juhl M. Physical exercise and pelvic girdle pain in pregnancy: A nested case-control study within the Danish National Birth Cohort. *Sexual and Reproductive Healthcare*. 2015;6(4):198-203. doi:10.1016/j.srhc.2015.04.004
93. Hill B, McPhie S, Moran LJ, et al. Lifestyle intervention to prevent obesity during pregnancy: Implications and recommendations for research and implementation. *Midwifery*. 2017;49:13-18.
94. Thompson EL, Vamos CA, Daley EM. Physical activity during pregnancy and the role of theory in promoting positive behavior change: A systematic review. 2017. doi:10.1016/j.jshs.2015.08.001
95. Markland D, Ryan RM, Tobin VJ, Rollnick S. Motivational Interviewing and Self–Determination Theory. *Journal of Social and Clinical Psychology*. 2005;24(6):811-831.

doi:10.1521/jscp.2005.24.6.811

96. Hayes L, Mcparlin C, Kinnunen TI, Poston L, Robson SC, Bell R. Change in level of physical activity during pregnancy in obese women: findings from the UPBEAT pilot trial. *BMC Pregnancy and Childbirth*. 2015;15(52):1-8. doi:10.1186/s12884-015-0479-2
97. Phelan S. Pregnancy: A "teachable moment" for weight control and obesity prevention. *Am J Obstet Gynecol*. 2010;202(2):1-16. doi:10.1016/j.ajog.2009.06.008.Pregnancy
98. Heslehurst N, Hayes L, Jones D, et al. The effectiveness of smoking cessation, alcohol reduction, diet and physical activity interventions in changing behaviours during pregnancy: A systematic review of systematic reviews. *PLoS ONE*. 2020;15(5). doi:10.1371/journal.pone.0232774
99. Phelan S. Windows of Opportunity for Lifestyle Interventions to Prevent Gestational Diabetes Mellitus. doi:10.1055/s-0036-1586504
100. Rockliffe L, Peters S, Heazell AEP, Smith DM. Factors influencing health behaviour change during pregnancy: a systematic review and meta-synthesis. *Health Psychology Review*. 2021;15(4):613-632. doi:10.1080/17437199.2021.1938632
101. Moholdt T, Hawley JA. Maternal Lifestyle Interventions: Targeting Preconception Health. *Trends in Endocrinology and Metabolism*. 2020:1-9.
102. Connolly CP, Conger SA, Montoye AHK, et al. Walking for health during pregnancy: A literature review and considerations for future research. *Journal of sport and health science*. 2019;8(5):401-411. doi:10.1016/J.JSHS.2018.11.004
103. Slaght J, Sénéchal M, Hrubeniuk TJ, Mayo A, Bouchard DR. Walking Cadence to Exercise at Moderate Intensity for Adults: A Systematic Review. *Journal of Sports Medicine*. 2017;2017:1-12. doi:10.1155/2017/4641203
104. Davenport MH, Marchand A, Mottola MF, et al. Exercise for the prevention and treatment of low back, pelvic girdle and lumbopelvic pain during pregnancy: a systematic review and meta-analysis. *Br J Sports Med*. 2019;53(2):90-98.
105. Germini F, Noronha N, Borg Debono V, et al. Accuracy and Acceptability of Wrist-Wearable Activity Tracking Devices: A Systematic Review of the Literature. *Journal of Medical Internet Research*. 2022;24(1):1-18.
106. Evenson KR, Spade CL. Review of Validity and Reliability of Garmin Activity Trackers. *Journal for the Measurement of Physical Behaviour*. 2020;3(2):170-185.
107. Fuller D, Colwell E, Low J, et al. Reliability and Validity of Commercially Available

Wearable Devices for Measuring Steps, Energy Expenditure, and Heart Rate: Systematic Review. *JMIR mHealth and uHealth*. 2020;8(9):1-23.

108. Da Silva DF, Mohammad S, Hutchinson KA, Adamo KB. Cross-Validation of Ratings of Perceived Exertion Derived from Heart Rate Target Ranges Recommended for Pregnant Women. *International journal of exercise science*. 2020;13(3):1340-1351.
109. Speakman JR, Yamada Y, Sagayama H, et al. A standard calculation methodology for human doubly labeled water studies. *Cell Reports Medicine*. 2021;2(2):100203. doi:10.1016/J.XCRM.2021.100203
110. Westerterp KR. Assessment of physical activity: a critical appraisal. *European journal of applied physiology*. 2009;105(6):823-828. doi:10.1007/S00421-009-1000-2
111. Dowd KP, Szeklicki R, Minetto MA, et al. *A Systematic Literature Review of Reviews on Techniques for Physical Activity Measurement in Adults: A DEDIPAC Study*. Vol 15. International Journal of Behavioral Nutrition and Physical Activity; 2018. doi:10.1186/s12966-017-0636-2
112. Hronek M, Zadak Z, Hrnciarikova D, Hyspler R, Ticha A. New equation for the prediction of resting energy expenditure during pregnancy. *Nutrition (Burbank, Los Angeles County, Calif)*. 2009;25(9):947-953. doi:10.1016/J.NUT.2009.02.011
113. Löf M. Physical activity pattern and activity energy expenditure in healthy pregnant and non-pregnant Swedish women. *European Journal of Clinical Nutrition*. 2011;65129(10):1295-1301. doi:10.1038/ejcn.2011.129
114. Prentice AM. Stable isotopic methods for measuring energy expenditure. Applications of the doubly-labelled-water (2H2(18)O) method in free-living adults. *The Proceedings of the Nutrition Society*. 1988;47(3):259-268. doi:10.1079/PNS19880043
115. Sallis JF, Saelens BE. Assessment of Physical Activity by Self-Report: Status, Limitations, and Future Directions. *https://doi.org/101080/02701367200011082780*. 2015;71:1-14. doi:10.1080/02701367.2000.11082780
116. Sattler MC, Jaunig J, Watson ED, et al. Physical Activity Questionnaires for Pregnancy: A Systematic Review of Measurement Properties. *Sports Medicine*. 2018;48(10):2317-2346. doi:10.1007/s40279-018-0961-x
117. Helmerhorst HJF, Brage S, Warren J, Besson H, Ekelund U. A systematic review of reliability and objective criterion-related validity of physical activity questionnaires. *The international journal of behavioral nutrition and physical activity*. 2012;9.

doi:10.1186/1479-5868-9-103

118. Chandonnet N, Saey D, Alméras N, Marc I. French pregnancy physical activity questionnaire compared with an accelerometer cut point to classify physical activity among pregnant obese women. *PLoS ONE*. 2012;7(6). doi:10.1371/journal.pone.0038818
119. Coll-Risco I, Camiletti-Moirón D, Acosta-Manzano P, Aparicio VA. Translation and cross-cultural adaptation of the Pregnancy Physical Activity Questionnaire (PPAQ) into Spanish. *The Journal of Maternal-Fetal & Neonatal Medicine*. 2018;80(4):290-298. doi:10.1080/14767058.2018.1479849
120. Papazian T, El Osta N, Hout H, et al. Pregnancy physical activity questionnaire (PPAQ): Translation and cross cultural adaption of an Arabic version. *PLoS ONE*. 2020;15(3). doi:10.1371/JOURNAL.PONE.0230420
121. Johnson RB, Onwuegbuzie AJ. Toward a Definition of Mixed Methods Research. *Journal of Mixed Methods Research*. 2007;1(2):112-133. doi:10.1177/1558689806298224
122. Creswell, J.W., Clark VL. Designing & conducting mixed methods research + the mixed methods reader. *Designing & conducting mixed methods research + the mixed methods reader*. 2017;1(2):24-27.
123. Dasgupta K, Maindal HT, Nielsen KK, O'reilly S. Achieving penetration and participation in diabetes after pregnancy prevention interventions following gestational diabetes: A health promotion challenge. 2018. doi:10.1016/j.diabres.2018.04.016
124. Backhausen MG, Tabor A, Albert H, Rosthøj S, Damm P, Hegaard HK. The effects of an unsupervised water exercise program on low back pain and sick leave among healthy pregnant women - A randomised controlled trial. *PloS one*. 2017;12(9):1-16.
125. Vinter CA, Jensen DM, Ovesen P, Beck-nielsen H, Jørgensen JS. The LiP (Lifestyle in Pregnancy) Study. *Diabetes Care*. 2011;34:2502-2507.
126. Danmarks Statistik. Statistikbanktabeller på kommuneniveau. https://www.dst.dk/da/Statistik/kommunekort/statistikbanktabeller-paa-kommuneniveau. Published 2021.
127. Choi J, Lee M, Lee J-K, Kang D, Choi J-Y. Correlates associated with participation in physical activity among adults: a systematic review of reviews and update. doi:10.1186/s12889-017-4255-2
128. Meah VL, Davies GA, Davenport MH. Why can't i exercise during pregnancy? Time to revisit medical "absolute" and "relative" contraindications: Systematic review of evidence of

harm and a call to action. *British Journal of Sports Medicine*. 2020;54(23):1395-1404.

129. Lindqvist M, Lindkvist M, Eurenius E, Persson M, Ivarsson A, Mogren I. Leisure time physical activity among pregnant women and its associations with maternal characteristics and pregnancy outcomes. *Sexual & Reproductive Healthcare*. 2016;9:14-20. doi:10.1016/j.srhc.2016.03.006
130. Brickwood KJ, Watson G, O'brien J, Williams AD. Consumer-based wearable activity trackers increase physical activity participation: Systematic review and meta-analysis. *JMIR mHealth and uHealth*. 2019;7(4). doi:10.2196/11819
131. Larsen RT, Wagner V, Korfitsen CB, et al. Effectiveness of physical activity monitors in adults : systematic review and meta-analysis. 2022:1-15. doi:10.1136/bmj-2021-068047
132. Laranjo L, DIng Di, Heleno B, et al. Do smartphone applications and activity trackers increase physical activity in adults? Systematic review, meta-analysis and metaregression. *British Journal of Sports Medicine*. 2021;55(8):422-432. doi:10.1136/bjsports-2020-102892
133. Silva-Jose C, Nagpal TS, Coterón J, Barakat R, Mottola MF. The 'new normal' includes online prenatal exercise: exploring pregnant women's experiences during the pandemic and the role of virtual group fitness on maternal mental health. *BMC Pregnancy and Childbirth*. 2022;22(1):251. doi:10.1186/S12884-022-04587-1
134. Hillyard M, Sinclair M, Murphy M, Casson K, Mulligan C. The impact of COVID-19 on the physical activity and sedentary behaviour levels of pregnant women with gestational diabetes. Mullins E, ed. *PLoS ONE*. 2021;16(8 August):e0254364. doi:10.1371/journal.pone.0254364
135. Whitaker KM, Hung P, Alberg AJ, Hair NL, Liu J. Variations in health behaviors among pregnant women during the COVID-19 pandemic. *Midwifery*. 2021;95:102929. doi:10.1016/J.MIDW.2021.102929
136. Schmidt T, Pawlowski CS. Physical Activity in Crisis: The Impact of COVID-19 on Danes' Physical Activity Behavior. *Frontiers in Sports and Active Living*. 2020;2:610255. doi:10.3389/FSPOR.2020.610255
137. Flannery C, Mchugh S, Anaba AE, et al. Enablers and barriers to physical activity in overweight and obese pregnant women: an analysis informed by the theoretical domains framework and COM-B model. *BMC Pregnancy & Childbirth*. 2018;18(178):1-13.
138. Bauer C, Graf C, Platschek A, Strüder H, Ferrari N. Reasons, Motivational Factors and Perceived Personal Barriers to Engagement in Physical Activity During Pregnancy Vary

Within the BMI Casses – The Prenatal Prevention Project Germany. *Journal of Physical Activity and Health*. 2017.

139. Jelsma JGM, Van Leeuwen KM, Oostdam N, et al. Beliefs, Barriers, and Preferences of European Overweight Women to Adopt a Healthier Lifestyle in Pregnancy to Minimize Risk of Developing Gestational Diabetes Mellitus: An Explorative Study. *Journal of Pregnancy*. 2016:1-11.
140. Ong MJ, Wallman KE, Fournier PA, Newnham JP, Guelfi KJ. Enhancing energy expenditure and enjoyment of exercise during pregnancy through the addition of brief higher intensity intervals to traditional continuous moderate intensity cycling. *BMC Pregnancy and Childbirth*. 2016;16(1):1-6.
141. Australian Government. Department of Health. Physical activity and exercise guidelines for pregnancy.
142. Brown WJ, Hayman M, Haakstad LAH, et al. Australian Guidelines for Physical Activity in pregnancy and postpartum. *Journal of Science and Medicine in Sport*. 2022;(xxxx). doi:10.1016/j.jsams.2022.03.008

Paper 1

BMJ Open

Structured supervised exercise training or motivational counselling during pregnancy on physical activity level and health of mother and offspring: FitMum study protocol

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ABSTRACT

Introduction A physically active lifestyle during pregnancy improves maternal and offspring health but can be difficult to follow. In Denmark, less than 40% of pregnant women meet physical activity (PA) recommendations. The FitMum study aims to explore strategies to increase PA during pregnancy among women with low PA and assess the health effects of PA. This paper presents the FitMum protocol, which evaluates the effects of structured supervised exercise training or motivational counselling supported by health technology during pregnancy on PA level and health of mother and offspring.

Methods and analysis A single-site three-arm randomised controlled trial that aims to recruit 220 healthy, pregnant women with gestational age (GA) no later than week 15 and whose PA level does not exceed one hour/week. Participants are randomised to one of three groups: structured supervised exercise training consisting of three weekly exercise sessions, motivational counselling supported by health technology or a control group receiving standard care. The interventions take place from randomisation until delivery. The primary outcome is min/week of moderate-to-vigorous intensity PA (MVPA) as determined by a commercial activity tracker, collected from randomisation until GA of 28 weeks and 0-6 days, and the secondary outcome is gestational weight gain (GWG). Additional outcomes are complementary measures of PA; clinical and psychological health parameters in participant, partner and offspring; analyses of blood, placenta and breastmilk samples; process evaluation of interventions; and personal understandings of PA.

Ethics and dissemination The study is approved by the Danish National Committee on Health Research Ethics (# H-18011067) and the Danish Data Protection Agency (# P-2019-512). Findings will be disseminated via peer-reviewed publications, at conferences, and to health professionals via science theatre performances.

Trial registration number NCT03679130.

Strengths and limitations of this study

- The efficacy of structured supervised exercise training and motivational counselling supported by health technology to improve physical activity and reduce weight gain of pregnant women is directly compared in a randomised controlled trial.
- The trial involves complex interventions and is held in one site only, so generalisability and fidelity might be a concern. Yet, as one of the additional outcomes, a process evaluation is conducted alongside the trial to explore how the interventions are carried out and adapted.
- The study is comprehensive and multidisciplinary in its design. Many different methodologies are used, and mother, partner and offspring are studied.
- Activity trackers can increase physical activity level and are feasible tools in everyday life, but commercial activity trackers have limited validity for the quantification of physical activity.
- Physical activity is extensively measured using three different methods: commercial activity trackers, gold standard doubly labelled water and the validated Pregnancy Physical Activity Questionnaire.

Protocol version This paper was written per the study protocol version 8 dated 28 August 2019.

INTRODUCTION

Although the health effects of PA are widely acknowledged, the means of how to best implement and maintain PA in everyday life are lacking.[1] Pregnancy can be regarded as a window of opportunity to implement good habits of PA as pregnant women are in regular contact with health professionals and are likely

motivated to adopt healthy behaviours, as illustrated by reduced alcohol consumption and smoking cessation.[2–4] However, pregnancy can be seen as an opportunity to be exempt from fitness demands and bodily ideals and can be experienced as a troublesome time due to fatigue and discomfort.[5 6] Moreover, pregnancy is a relatively short period of time in regards to forming new habits[6] and that may affect the motivations and challenges in being physically active. Furthermore, differences in work status, social relations and family situations, as well as varying material and structural conditions, may contribute to the implementation of PA.[7]

Insufficient PA is a global problem[8] that occurs also during pregnancy.[8–12] It is a significant public health issue, as increasing evidence suggests that lifestyle during pregnancy influences health in the mother and her offspring.[4 13] Regular PA during pregnancy promotes clinical and metabolic health in both mother and offspring and reduces the number of complications during pregnancy and delivery.[14–19] PA reduces GWG,[20–26] the risk of gestational diabetes mellitus,[27–32] the intensity of low back pain[33] and the risk of caesarean delivery[22 29 34–37] and improves maternal body composition.[38] Additionally, a physically active pregnancy improves the health of the offspring by normalising birth weight,[22] reducing the risk of preterm delivery[39 40] and improving neonatal body composition[41 42] as well as placental function,[43 44] which results in optimised intrauterine growth conditions.

The Danish Health Authorities recommend that healthy pregnant women are physically active for at least 30 min/day at moderate intensity,[45] but only 38% of Danish pregnant women achieve this recommended level.[46] Several barriers to PA during pregnancy are addressed in the literature,[47] including anxiety about overdoing exercise, low motivation to adopt an active lifestyle during pregnancy, changing energy levels throughout the pregnancy and lack of time to be physically active.[48] The latest recommendations on lifestyle interventions during pregnancy support individualised advice on how to increase the PA level rather than a generic approach,[6] as pregnant women prefer personalised information.[49] Consequently, policymakers, healthcare professionals and pregnant women advocate for evidence-based guidance on how to implement PA in everyday life during pregnancy safely and effectively, with approaches that meet the needs, preferences and choices of the pregnant woman.

During the past decades, many PA intervention studies in pregnant women have been conducted on overweight and obese populations[23 24 26 28 50–57] as well as in healthy normal-weight pregnant women.[20 21 32 33 58–61] Still, none of these studies have focused primarily on investigating the effect of the exercise interventions on actual PA level in pregnant women nor have they used novel objective methods to measure actual PA levels. Structured, supervised exercise training and motivational counselling have been applied separately in pregnant women,[20 21 23 24 26 28 32 33 50–55 58–63] but the relative efficacy of these interventions has not been compared; this hampers the evidence-based implementation of effective exercise programmes into everyday life.

Objective

This paper describes the protocol of the FitMum study, which is a randomised controlled trial (RCT). The FitMum RCT aims to evaluate the effects of structured supervised exercise training (EXE) and motivational counselling supported by health technology (MOT) compared with standard care (CON) on PA level and GWG during pregnancy. Additional aims of the study are to investigate the effects of EXE and MOT on clinical and metabolic health parameters in both mother and offspring. We will also explore how the FitMum exercise programmes are carried out and adopted by conducting a process evaluation. In addition, we explore the personal attribution of meaning to the experiences and practices of PA among participants. Furthermore, we investigate how social, structural and cultural factors facilitate or hinder the successful implementation of exercise during pregnancy.

METHODS

Study design

The FitMum RCT is a single-site, three-arm randomised controlled trial study.

Setting

The study is carried out at the Department of Gynaecology and Obstetrics, Nordsjaellands Hospital (NOH), Hillerod, in the Capital region of Denmark, where approximately 4000 women give birth per year. NOH is a public hospital, and participation in FitMum is free of charge.

Participants

This study aims to include 220 healthy, pregnant women. Inclusion criteria are obtained written informed consent, maternal age of 18 years or older, gestational age (GA) of maximum 15 weeks, ultrasonic-confirmed viable intrauterine pregnancy, body mass index of 18.5–45 kg/m^2 and body weight <150 kg (prepregnancy weight or first measured weight in pregnancy), ability to wear a wrist-worn activity tracker 24/7 until one year postpartum and having a smartphone. Exclusion criteria are structured exercise at moderate-to-vigorous intensity for more than one hour/week during early pregnancy, previous preterm delivery, obstetric or medical complications, multiple pregnancies, inability to speak Danish, or alcohol or drug abuse.

Recruitment and inclusion

Participants are recruited: (1) *via* booking confirmation of a first-trimester scan, (2) at face-to-face meetings during the first-trimester scan and (3) through posters, flyers and social media. Before inclusion, interested women answer an online, one-page prescreening questionnaire. Eligible participants and their partners are invited to the first

visit at NOH as soon as possible and no later than GA of 14 weeks and 6 days. At visit 1, the woman is verbally informed about the study and screened according to inclusion and exclusion criteria. Women who have not had a first-trimester scan are vaginally scanned to confirm a singleton, viable intrauterine pregnancy. All eligible women are included, and written informed consent is obtained (online supplemental file 1). Written informed consent is also obtained from the partner as biological samples are collected from the offspring and from the partner (online supplemental file 2). After inclusion, we obtain anthropometric and demographic information, a blood sample as well as a short semistructured interview with the participant. The interview provides knowledge of the participant's thoughts on participating in a research project, knowledge of prior and current PA level, and experiences with health technologies.

At the end of visit 1, the participant receives a commercial activity tracker, Garmin Vivosport. The participant is instructed to wear the tracker continuously 24/7 from the one week baseline period until one year postpartum, except during charging. The activity tracker is water resistant and determines the frequency, duration and intensity of activity periods on a minute-to-minute basis. The data from the activity tracker are wirelessly synced to the associated app, Garmin Connect, provided by Garmin International, and the research platform Fitabase (Small Steps Labs LLC), through which the compliance of wearing and synchronising the data from the tracker are continuously monitored during the study.

Baseline period and randomisation

After inclusion, the baseline PA level of the participant is measured by the activity tracker for one week. After the baseline period, participants are randomised into the EXE, MOT and CON groups (figure 1). The target number of participants randomised to each group is 88, 88 and 44, respectively, in order to have more participants in the intervention groups. Randomisation is performed via a numbered randomisation list administered

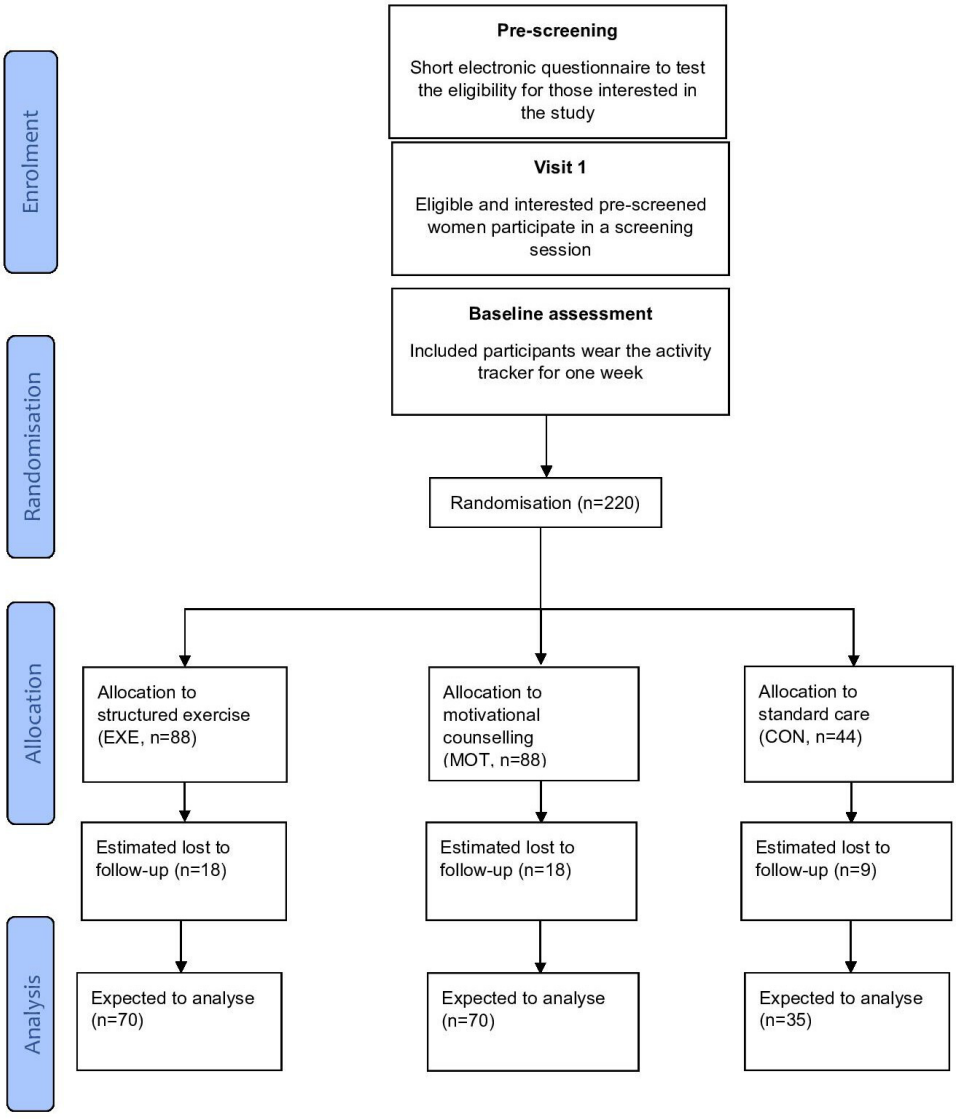

Figure 1 Flow diagram of the FitMum RCT.

through the database Research Electronic Data Capture (REDCap), and the investigators are blinded to the procedure. Blinding of participants is considered impossible due to the inherent content of the exercise interventions. The participant is informed about the assigned group by email, and participants in EXE and MOT receive written information containing guidelines from the Danish Health Authorities about PA during pregnancy.

Patient and public involvement

Template for Intervention Description and Replication[64] was used as inspiration for the development and description of the study. As a part of the development phase, stakeholders in the field were involved in discussions and sharing of knowledge. Additionally, 27 semistructured interviews with Danish pregnant women, midwives and obstetricians were performed to explore the feasibility of such a study as well as the motivational factors and barriers to PA during pregnancy. Participants are not directly involved in the recruitment and conduct of the study, but a process evaluation is conducted, and personal understandings of the participants are obtained via interviews (see further). The insights from the study will be shared with the participants at an information meeting after the end of the study.

Interventions

Standard care at the hospital

All three groups are offered the standard care that applies to women giving birth at NOH. This consists of three appointments with their general practitioner (GA weeks 6–10, 25 and 32), five to six midwife consultations (GA weeks 14–17, 29, 36, 38, 40 and if still pregnant around week 41 as well) and ultrasonic scans at GA weeks 12 and 20.

Standard care control group (CON)

Participants in CON wear an activity tracker to determine their activity level. The face of the tracker looks like a normal watch showing only time and battery life.

Structured supervised exercise training intervention (EXE)

The targeted PA level for all participants in EXE and MOT is at least 30 min/day at a moderate intensity as recommended to healthy pregnant women,[6] and all participants are informed hereof if randomised to EXE or MOT. In EXE, exercise training takes place in teams and is supervised by health professionals (exercise physiologists, physiotherapists and public health scientists). It consists of three weekly 1-hour exercise sessions at moderate intensity, including two exercise sessions in a gym and one in a public swimming pool. The gym sessions consist of a combination of aerobic and resistance training with 30 min stationary bike training (a combination of hill climbing and high cadence intervals) and 30 min of other exercise, for example, elastic bands, exercise balls, mats, dumbbells or body weight. In the swimming pool, participants do 15 min of swimming and 45 min of water exercises with plates, balls, dumbbells or body weight. Moderate intensity during training sessions is assessed using both heart rate monitoring of 65%–80% of age-predicted maximal heart rate (from the activity tracker) and perceived exertion in the range of 12–14 on Borg's conventional 6–20 point scale,[64] as recommended by the American College of Obstetricians and Gynaecologists.[14] If a participant experiences any pain or needs to decrease intensity, the content of exercise sessions (repetitions and/or resistance) is individually adjusted accordingly. Special attention is paid to the newly recruited participants. Exercise sessions are offered at seven different times per week, and participants are recommended to sign up for three of these sessions. The sessions are held early mornings or late afternoons all weekdays and before noon on Fridays and Saturdays.

Motivational counselling supported by health technology (MOT)

This intervention is composed of four individual and three group counselling sessions as well as weekly SMS reminders. The overall focus of both the individual and group counselling sessions is based on what already motivates the participants to increase or maintain their PA level. The motivation technique applied is inspired by motivational interviewing,[65] self-determination theory[66] and behaviour change techniques.[67]

All four *individual sessions* last one hour and are led by professional health counsellors (exercise physiologists, physiotherapists and public health scientists). The sessions aim to discuss the participant's barriers, wishes, needs, knowledge and former PA experiences to identify individual characteristics and motivation towards a more physically active lifestyle. Aside from measuring the PA level, the activity trackers are also used as an intervention element to motivate the participants to increase their PA levels.[68] During individual sessions, feedback on recent PA performances is provided based on activity data acquired from the activity tracker, in order to give the participants insight into their PA level. The participants will, with guidance from the counsellor, set their own activity goals and make an individual action plan to increase the PA level, which may have a motivating effect on PA behaviour.[68 69] Individual sessions are scheduled during the daytime as conveniently for the participant as possible.

The first *group session* lasts one hour and aims to inform the participants about guidelines for PA, benefits associated with PA during pregnancy and possible ways to increase PA during pregnancy. In the following two 2-hour group sessions, the interaction between the participants is used to create meaningful group processes such as support, experience exchange, reflection, learning and development. These sessions focus on the discussion of relevant topics concerning PA during pregnancy, and the counsellor acts as a facilitator through the session, with the topics of conversation chosen by the participants. Issues like postpartum PA, the pelvic floor, uterine contractions, abdominal muscles and diastasis recti, and myths about pregnancy PA are discussed. Group sessions

are held late afternoons or before noon for those on maternity leave.

The weekly SMS reminders have supportive and motivating content and are used to encourage the participants to achieve a moderate PA level. The texts are chosen based on every participant's PA level during the last week measured by the activity tracker. One example of the text: 'You have been exercising regularly for an extended period of time. Well done. Good habits make it easier for you to continue as your belly gets bigger and heavier'.

Outcome measures

The data collection procedures are illustrated in table 1.

Primary outcome: moderate-to-vigorous intensity physical activity

The primary outcome of FitMum RCT is min/week of MVPA measured continuously from randomisation to GA of 28 weeks and 0-6 days as determined by a wrist-worn activity tracker, Garmin Vivosport, with a built-in heart rate monitor and accelerometer.

Secondary outcome: gestational weight gain

Body weight of the participant before pregnancy is self-reported. The body weight during pregnancy is measured four times from inclusion until delivery on the same scale (Seca 799) with the participant in light clothes and without shoes.

Additional outcomes

Complementary measures of physical activity

Complementary measures of PA are obtained by the Danish version of 'Pregnancy Physical Activity Questionnaire' (PPAQ)[70] named PPAQ-DK and by the doubly labelled water technique.[71]

PPAQ is a semiquantitative and subjective instrument, which has been validated[70] and is considered one of the most valid and reliable questionnaires for the assessment of PA level in pregnant women.[72] Our research group has translated PPAQ to Danish and validated it in a Danish pregnant population.[73]

The doubly labelled water technique is the 'gold standard' technique to measure free-living energy expenditure objectively and is safe, even for pregnant women, as it relies on stable, non-radioactive isotopes.[74–77] The participants are administered a glass of water for oral intake containing 0.1 g of 99.8% $^{2}H_2O$ and 1.6 g of 10% ^{18}O per kg body weight. In total, five postdose urine samples are collected in the morning (not the first urine void of the day); on the day after oral water dosage; and after four, seven, 11 and 14 days. The urine samples are stored in the participant's freezer and later at −80°C.

In addition, the PA of the participants is determined from GA week 29 until delivery and in the first year postpartum by the activity tracker. The measures of PA include active calories, active time, steps, heart rate, moderate-intensity and vigorous-intensity activity, floors climbed, MET-min/week and type of activity, which is recognised automatically by the tracker.

Clinical and psychological health parameters in participant, partner and offspring

A variety of clinical and psychological health parameters are obtained from the participant, her partner and her offspring. *Clinical data* regarding pregnancy, delivery and neonatal outcomes are collected from medical records. *Health-related quality of life* is determined in the participant by the Danish version of the Medical Outcomes Study Short Form 36,[78 79] which has also been validated in pregnant women.[80] *Exercise self-efficacy* is determined by the Danish version of the Pregnancy Exercise Self-Efficacy Scale (P-ESES).[81] P-ESES has been translated into Danish and validated in a Danish pregnant population by our research group.[82] *PA motivation* is determined by the Danish version of the Behavioural Regulation in Exercise Questionnaire (BREQ-2),[83–85] which is the most widely used measure of the continuum of behavioural regulation in exercise psychology research. *Sleep quantity and quality* are assessed in the participant by the activity tracker and by the Danish version of the self-administered questionnaire Pittsburgh Sleep Quality Index (PSQI).[86 87] The PSQI is considered a valid and reliable tool to assess sleep metrics among pregnant women.[88] In addition, a validation of activity trackers to measure sleep will be conducted using polysomnography in a subgroup of women already participating in the FitMum study. *Sick leave and pelvic and low back pain* are registered by asking the participant whether she has been absent from work/study and on sick leave during her pregnancy and whether she has experienced pelvic and/or low back pain before and during her pregnancy. *Maternal body composition* is determined from total body water measured by doubly labelled water technique and by a postpartum dual-energy X-ray absorptiometry (DXA) scan. *Offspring growth:* head circumference, length and weight is measured at birth and by general practitioners at five weeks, five months and 12 months postpartum. Participants receive an electronic questionnaire and fill out the anthropometric data along with information on offspring dietary habits and vaccine status. *Parental mental well-being* is assessed six to eight weeks after birth. Both parents or holders of custody receive a questionnaire consisting of the Edinburgh Postnatal Depression Score and Gotland Depression Scale, which are combined as a screening tool for postnatal depression[89–92] in Danish postnatal care. *Psychomotor development of the offspring* is assessed by the validated Ages and Stages Questionnaire 3 (ASQ-3), which is administered electronically to participants 12 months after the due date. ASQ-3 pinpoints developmental progress in the fields of communication, gross motor, fine motor, problem solving and personal-social skills. The administration of ASQ-3 relative to due date and not to birth date aims to correct for variance in cognitive and motor skills due to premature birth. *Offspring physical activity* is assessed for seven days by an infant activity tracker (Actigraph GT3X+) 12 months after the due date. The tracker detects level, intensity and pattern of physical activity.

Table 1 Procedures and measurements in FitMum RCT

Visit number	Visit 1	Email randomisation	Visit 2	Visit 3	Visit 4	Visit 5	
Gestational age (week+days)	Screening and baseline testing max. 15+0	One week after inclusion	Week 28+0–6	Week 34+0–6	Delivery Approximately week 40	7–14 days after delivery	One year after delivery
Ultrasound scan	×						
Oral information about the study	×						
Medical interview to assess inclusion and exclusion criteria	×						
Demographic, anthropometric, sickness absence and pelvic/low back pain data	×		×	×		×	
Medical history, concomitant disease and previous medication	×						
Demographic and anthropometric data of the participant's partner	×						
Written informed consent	×						
Activity tracker and associated oral and written information	×						
Randomisation		×					
Methodology for obtaining outcomes							
Activity tracker	Continuously during the trial and one year after delivery						
Maternal body weight	×		×	×	×	×	Six times at home during the first year postpartum
Doubly labelled water			×				
Questionnaires: PPAQ-DK, SF-36, PSQI, P-ESES, BREQ-2	×		×	×			×
Maternal blood samples	×		×	×	×		
Paternal blood sample					×		
Umbilical cord blood sample					×		
Placenta samples					×		
DXA scan						×	
Breastmilk sample						×	
Qualitative interview	×			×			×
Observation and autodocumentation		Recurring					
ASQ-3							×
Growth assessment at general practitioner							Five weeks, and five and 12 months
Parental mental well-being questionnaire							Six to eight weeks postpartum
7-day child accelerometer							×
Safety							
Record adverse events			×	×			
Symphysis-fundal height			×	×			

ASQ-3, Ages and Stages Questionnaire 3; BREQ-2, Behavioural Regulations Exercise Questionnaire; DXA, dual-energy X-ray absorptiometry; PA, physical activity; P-ESES, Pregnancy Exercise Self-efficacy Scale; PPAQ-DK, Pregnancy Physical Activity Questionnaire (Danish version); PSQI, Pittsburgh Sleep Quality Index; SF-36, The Medical Outcomes Study Short Form 36.

Analyses of blood, placenta and breastmilk samples

Plasma metabolites and hormones are assessed in maternal and paternal venous blood. The blood samples will be analysed for concentrations of glucose, cholesterol (total, high and low density), triglyceride, free fatty acids, amino acids, interleukin-6, and C reactive protein. Venous blood is obtained from the umbilical cord within 30 min after delivery of the placenta. The blood will be analysed for concentrations of glucose, cholesterol (total, high and low density), triglyceride, insulin, c-peptide, free fatty

acids, amino acids, adiponectin and leptin. Furthermore, epigenetic profiling at the level of *DNA methylation* will be performed in maternal, paternal and umbilical cord blood mononuclear cells. Bioinformatic comparison of DNA methylomes from parents and offspring will infer on the DNA methylation marks that are modulated by maternal exercise and transmitted to the offspring. Information on DNA methylomes from each parent will allow us to distinguish between maternally and paternally epigenetic profiles transmitted to the offspring. Principal component analyses will be used to identify the specific metabolic or anthropometric features of the mother that are associated with a specific DNA methylation footprint transmitted to the offspring. *Placental function* is assessed from samples taken within 30 min after delivery of the placenta. The samples are immediately frozen on dry ice and stored at −80°C. Analyses will include RNA-seq, non-targeted metabolomics, RT-qPCR, Western blot, histology and immunohistochemistry. *Breastmilk* is obtained from a single feed at the day of visit 5 and stored at −80°C for later metabolomic and lipidomic analyses.

Process evaluation of interventions

A process evaluation is made using quantitative and qualitative methods to provide insight into mechanisms through which interventions bring about change, assess fidelity and quality of implementation, clarify causal mechanisms and identify contextual factors associated with variations in outcomes.[93–95] Integrating process evaluations alongside outcome data is recommended by the UK Medical Research Council guidelines in order to develop and evaluate complex interventions to improve the interpretation of the outcomes, design more effective interventions and apply interventions appropriately across groups and settings by understanding the implementation and functioning of interventions in a given context.[94 96] The Reach, Effectiveness, Adoption, Implementation, and Maintenance framework is used to improve reporting on key issues related to the implementation and external validity of FitMum RCT.[97]

Personal understandings of physical activity

The qualitative dataset is composed of 220 short standardised screening interviews, 30 semistructured interviews, 70 observations, five sets of autoethnographies, visual material, as well as drop-out and follow-up interviews. This subproject will explore the physical and mental health and well-being of the participants, their social relations, PA levels and their experience of pregnancy to identify the challenges and barriers of PA during pregnancy. Personal understandings of PA in the everyday life of participants are determined at inclusion, GA week 34 and one year postpartum, in approximately ten participants from each of the three study groups.

Changes during the COVID-19 pandemic

Due to the COVID-19 pandemic (present in Denmark from 11 March 2020), supplies of interventions (EXE and MOT) and visits are periodically changed. During the lockdown period in spring 2020, all visits (except birth) are converted into online versions using Zoom Cloud Meetings or telephone. From 11 March 2020, in EXE, the swimming pool sessions are replaced with online land exercises and all land exercise sessions consist of 30 min of aerobic exercise where the participants exercise on their own (eg, biking, power-walking, dancing and aerobics) followed by 30 min of supervised online group resistance training. All individual and group MOT sessions are held online.

As much data as possible are collected during the pandemic, but some clinical data have not been possible to obtain in all participants due to limitations on non-urgent visits to the hospital. No blood samples are obtained at the virtual 'visits', women are weighed at home and symphysis-fundal height measurements are not obtained. No doubly labelled water is administered at the virtual 'visit' 2. The participant's body weight at visit 4 is noted by the midwives on the day of giving birth, but biological samples are not collected. No DXA scans or breastmilk samples are collected at 'visit' 5.

Data management and analysis

Data management

The activity tracker data are collected by Fitabase, which regularly backs up the data. A participant who does not synchronise the tracker for seven days or more is reminded by email, text message or phone call. All tracker data are exported from Fitabase to R[98] for data analysis. Tracker data are used to calculate non-wear time; a week is included in the analysis if the week has four or more days with complete data. A day that has six hours or more of non-wear time is excluded and considered a missing day. An electronic case report form (e-CRF) is used to collect all clinical data related to the trial. Data are stored in coded form according to the rules of the Danish Data Protection Agency. Personal data processing complies with the Act on Processing of Personal Data. Data are owned by NOH and University of Copenhagen. Use of data generated in FitMum RCT in new contexts must be agreed and approved by the Steering group. Technical University of Denmark and Aarhus University must have access to the data they have collected and are free to use it in new contexts. The e-CRF is completed by the investigators at the time of the participant's visits at NOH so that it always reflects the latest observations of the participant. Data will be stored for ten years, after which they will be transferred to the Danish National Archives 'Rigsarkivet' in an anonymised format.

Sample size

FitMum RCT has been powered to detect an overall significant difference in the primary outcome between the three groups as well as a significant difference between the two intervention groups (EXE vs MOT) with average activity levels of 210 (EXE), 150 (MOT) and 60 (CON) min/week. The SD was set at 116 min/week and based

on the results from Oostdam *et al*.[51] The required sample size is determined to obtain a power of 80% with a family-wise significance level of 5%. The sample size calculation showed that the required number of participants is 35 in CON and 70 in each of the two intervention groups due to the randomisation ratio of 1:2:2 to CON, EXE and MOT, respectively. Based on an expected lost to follow-up rate of 20%, as seen in similar exercise studies in pregnant women,[28 32 33 51] we plan to include 44 participants in CON and 88 participants in each of the two intervention groups, making a total of 220 participants.

Statistical methods

Data analyses of both primary and secondary outcomes will be performed using intention-to-treat analyses. In addition, a dose–response model will be estimated to quantify the relationship between adherence to the intervention (proportion of attendances in the planned EXE and MOT sessions, respectively) and the activity level. Moreover, analyses describing associations between the level of physical activity (as measured by the activity tracker) and the secondary and additional outcomes will be performed. Baseline data will be reported as averages and SDs (medians and IQRs) or frequencies and proportions as appropriate. No interim analyses will be performed on the primary and secondary outcomes. The analysis of the primary outcome will be performed using a linear model with the randomisation group as a categorical covariate and with adjustment for baseline PA level. Hypothesis tests will be performed using likelihood ratio tests. Statistical analysis will be conducted using R.[98] Analyses of the primary outcome will be performed by a statistician blinded from the intervention allocations. Investigators will perform analyses of baseline data and secondary and additional outcomes under the supervision of a statistician. A full statistical analysis plan is published in ClinicalTrials.gov.[99]

Trial status

The recruitment of participants began in September 2018 and ended in October 2020. Data collection of the primary outcome is completed in spring 2021. Full data collection is expected to be complete in 2022.

Ethics and dissemination

The FitMum study adheres to the principles of the Helsinki declaration. The study is approved by the Danish National Committee on Health Research Ethics (# H-18011067) and the Danish Data Protection Agency (# P-2019-512).

All participants consent in written form before inclusion and are informed that participation in the FitMum study is voluntary. Participants are informed that they may withdraw from the study at any time and that withdrawal of consent will not affect any subsequent pregnancy and delivery processes at NOH. The participant has time to ask questions and is allowed 24 hours to deliberate on study participation before the obtainment of written informed consent.

FitMum RCT is designed based on recommendations of appropriate PA during pregnancy,[14 45 100 101] and although anatomic and physiological changes occur during pregnancy, PA during an uncomplicated pregnancy is safe.[14 22 29 40 60 102–105] All information about adverse events and serious adverse events are documented consecutively and will be reported. Participants will be discontinued from the intervention if they are at risk of preterm birth, if a cervical length below 25 mm is measured, if serious obstetric or medical complications occur, if investigators' assessment reveals that continuation in the trial would be detrimental to the participant's well-being or if intolerable adverse events occur.

The FitMum study will provide evidence-based knowledge that can contribute to improving national and international recommendations of PA during pregnancy and to new, effective and simple guidance to implement health technology-supported exercise programmes to pregnant women. Based on the results and process evaluation, the knowledge and tools from the FitMum study can be transformed into initiatives in municipalities and hospitals to improve the health and quality of life for both mother and child and can be used for preventing the development of lifestyle-related diseases across generations.

Findings will be submitted for publication in peer-reviewed scientific journals and disseminated at national and international conferences. In addition, results will be disseminated to the public in relevant media and to health professionals via science theatre performances.

DISCUSSION

The FitMum study aims to evaluate the effects of structured supervised exercise training and motivational counselling supported by health technology on PA level during pregnancy to generate evidence about *how* to implement PA in everyday life in healthy pregnant women. Previous studies have investigated the effect of different lifestyle interventions on various health outcomes in normal weight,[23 24 26 28 50–57] overweight and obese pregnant women.[20 21 32 33 58–61] However, none of these studies have focused primarily on investigating the effect of PA interventions on actual PA level determined by novel objective methods. In addition, the FitMum study compares the effect of two very different PA interventions to explore strategies to implement PA programmes into pregnant women's everyday life. Moreover, offspring of FitMum participants will be studied for one year after birth, whereby knowledge on the effect of PA during pregnancy on offspring health will be obtained. A limitation of the study is that the true effect of motivational counselling is not identified, as technology is an integral part of the MOT intervention.

Consumer-based wearable activity trackers tend to increase PA level when they are used as an intervention tool or as part of an intervention.[106] Activity trackers are

often relatively light weight, comfortable to wear and rechargeable.[107] In addition, using an activity tracker to measure PA during pregnancy is feasible, recommended[108] and has a reasonable compliance rate during pregnancy and after giving birth.[109] However, there are some challenges and limitations of using activity trackers in a long-term intervention study. First, the participants must recharge the device and synchronise their data approximately once per week, which burdens participants and challenges adherence and compliance. Second, we cannot control the interaction of CON participants with the tracker. Third, the main goal for the tracker's design is a comfortable wear, yet wearing the tracker for extended periods of time may cause skin irritation and discomfort.[110] Moreover, the unavailability of the raw data and algorithms used by the manufacturer creates a limitation in the validation of PA metrics.[107] Therefore, measuring PA by a variety of methods, and comparing these methods with the doubly labelled water technique (a gold standard method), will be used in order to obtain comprehensive measures of PA behaviours in FitMum participants.

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REFERENCES

1 Craike M, Hill B, Gaskin CJ, *et al*. Interventions to improve physical activity during pregnancy: a systematic review on issues of internal and external validity using the RE-AIM framework. *BJOG: Int J Obstet Gy* 2017;124:573–83.
2 Thangaratinam S, Rogozińska E, Jolly K, *et al*. Interventions to reduce or prevent obesity in pregnant women: a systematic review. *Health Technol Assess* 2012;16:1–8.
3 World Health Organisation (who). *Good maternal nutrition. The best start in life*, 2016.
4 Adamo KB, Ferraro ZM, Brett KE. Can we modify the intrauterine environment to halt the intergenerational cycle of obesity? *Int J Environ Res Public Health* 2012;9:1263–307.
5 Jelsma JGM, van Leeuwen KM, Oostdam N, *et al*. Beliefs, barriers, and preferences of European overweight women to adopt a healthier lifestyle in pregnancy to minimize risk of developing gestational diabetes mellitus: an explorative study. *J Pregnancy* 2016;2016:1–11.
6 Hill B, McPhie S, Moran LJ. Lifestyle intervention to prevent obesity during pregnancy: implications and recommendations for research and implementation. *Midwifery* 2016;2017:13–18.
7 Bønnelycke J, Sandholdt CT, Jespersen AP. Household collectives: resituating health promotion and physical activity. *Sociol Health Illn* 2019;41:533–48.
8 Borodulin K, Evenson KR, Herring AH. Physical activity patterns during pregnancy through postpartum. *BMC Womens Health* 2009;9:32.
9 Santo EC, Forbes PW, Oken E, *et al*. Determinants of physical activity frequency and provider advice during pregnancy. *BMC Pregnancy Childbirth* 2017;17:1–11.
10 Hegaard HK, Damm P, Hedegaard M, *et al*. Sports and leisure time physical activity during pregnancy in nulliparous women. *Matern Child Health J* 2011;15:806–13.
11 Owe KM, Nystad W, Bø K. Correlates of regular exercise during pregnancy: the Norwegian mother and child cohort study. *Scand J Med Sci Sports* 2009;19:637–45.
12 Richardsen KR, Falk RS, Jenum AK, *et al*. Predicting who fails to meet the physical activity guideline in pregnancy: a prospective study of objectively recorded physical activity in a population-based multi-ethnic cohort. *BMC Pregnancy Childbirth* 2016;16:1–11.
13 Barrès R, Zierath JR. The role of diet and exercise in the transgenerational epigenetic landscape of T2DM. *Nat Rev Endocrinol* 2016;12:441–51.
14 Committee on Obstetric Practice. Committee opinion: physical activity and exercise during pregnancy and the postpartum period. *Am Coll Obstet Gynecol* 2015;650:1–8.
15 Evenson KR, Barakat R, Brown WJ. Guidelines for physical activity during pregnancy: comparisons from around the world. *Am J Lifestyle Med* 2014;8:102–21.

16 Perales M, Artal RLA. Exercise during pregnancy. *JAMA* 2017;317:1113–4.
17 Moyer C, Reoyo OR, May L. The influence of prenatal exercise on offspring health: a review. *Clin Med Insights Womens Health* 2016;9:CMWH.S34670.
18 U.S. Department of Health and Human Services. 2018 Physical Activity Guidelines Advisory Committee Scientific Report To the Secretary of Health and Human. 2018 Phys Act Guidel Advis Comm Sci Report To Secr Heal Hum Serv [Internet]., 2018. Available: https://health.gov/paguidelines/second-edition/report/pdf/PAG_Advisory_Committee_Report.pdf
19 Mottola MF, Davenport MH, Ruchat S-M, *et al*. 2019 Canadian guideline for physical activity throughout pregnancy. *Br J Sports Med* 2018;52:1339–46.
20 Ruiz JR, Perales M, Pelaez M, *et al*. Supervised exercise-based intervention to prevent excessive gestational weight gain: a randomized controlled trial. *Mayo Clin Proc* 2013;88:1388–97.
21 Leung Hui A, Back L, Ludwig S. Effects of lifestyle intervention on dietary intake, physical activity level, and gestational weight gain in pregnant women with different pre-pregnancy body mass index in a randomized control trial. *BMC Pregnancy Childbirth* 2014;14:1–9.
22 Wiebe HW, Boulé NG, Chari R, *et al*. The effect of supervised prenatal exercise on fetal growth. *Obstet Gynecol* 2015;125:1185–94.
23 Poston L, Bell R, Croker H, *et al*. Effect of a behavioural intervention in obese pregnant women (the upbeat study): a multicentre, randomised controlled trial. *Lancet Diabetes Endocrinol* 2015;3:767–77.
24 Harrison CL, Lombard CB, Strauss BJ, *et al*. Optimizing healthy gestational weight gain in women at high risk of gestational diabetes: a randomized controlled trial. *Obesity* 2013;21:904–9.
25 Vinter CA, Jensen DM, Ovesen P. The lip (lifestyle in pregnancy) study. *Diabetes Care* 2011;34:2502–7.
26 Renault KM, Nørgaard K, Nilas L, *et al*. The treatment of obese pregnant women (top) study: a randomized controlled trial of the effect of physical activity intervention assessed by pedometer with or without dietary intervention in obese pregnant women. *Am J Obstet Gynecol* 2014;210:134.e1–134.e9.
27 Russo LM, Nobles C, Ertel KA. Physical activity interventions in pregnancy and risk of gestational diabetes mellitus a systematic review and meta-analysis. *Obstet Gynecol* 2015;125:576–82.
28 Wang C, Wei Y, Zhang X. A randomized clinical trial of exercise during pregnancy to prevent gestational diabetes mellitus and improve pregnancy outcome in overweight and obese pregnant women. *Am J Obstet Gynecol* 2017:1–30.
29 Di Mascio D, Magro-Malosso ER, Saccone G, *et al*. Exercise during pregnancy in normal-weight women and risk of preterm birth: a systematic review and meta-analysis of randomized controlled trials. *Am J Obstet Gynecol* 2016;215:561–71.
30 Sanabria-Martínez G, García-Hermoso A, Poyatos-León R, *et al*. Effectiveness of physical activity interventions on preventing gestational diabetes mellitus and excessive maternal weight gain: a meta-analysis. *BJOG: Int J Obstet Gy* 2015;122:1167–74.
31 Koivusalo SB, Rönö K, Klemetti MM, *et al*. Gestational diabetes mellitus can be prevented by lifestyle intervention: the Finnish gestational diabetes prevention study (RADIEL): a randomized controlled trial. *Diabetes Care* 2016;39:24–30.
32 Barakat R, Perales M, Cordero Y. Influence of land or water exercise in pregnancy on outcomes: a cross-sectional study. *Med Sci Sports Exerc* 2017;49:1397–403.
33 Backhausen MG, Tabor A, Albert H, *et al*. The effects of an unsupervised water exercise program on low back pain and sick leave among healthy pregnant women – a randomised controlled trial. *PLoS One* 2017;12:e0182114.
34 Barakat R, Pelaez M, Lopez C, *et al*. Exercise during pregnancy reduces the rate of cesarean and instrumental deliveries: results of a randomized controlled trial. *J Matern Fetal Neonatal Med* 2012;25:2372–6.
35 Nielsen EN, Andersen PK, Hegaard HK, *et al*. Mode of delivery according to leisure time physical activity before and during pregnancy: a multicenter cohort study of low-risk women. *J Pregnancy* 2017;2017:1–8.
36 Dumith SC, Domingues MR, a M-SR. Physical activity during pregnancy and its association with maternal and child health indicators. *Rev Saude Publica* 2012;46:327–33.
37 Owe KM, Nystad W, Stigum H, *et al*. Exercise during pregnancy and risk of cesarean delivery in nulliparous women: a large population-based cohort study. *Am J Obstet Gynecol* 2016;215:791.e1–e13.
38 Ferrari N, Bae-Gartz I, Bauer C. Exercise during pregnancy and its impact on mothers and offspring in humans and mice. *J Dev Orig Health Dis* 2017:1–14.
39 Huang L, Fan L, Ding P. Maternal exercise during pregnancy reduces the risk of preterm birth through the mediating role of placenta. *J Matern Neonatal Med* 2017;7058:1–21.
40 Magro-Malosso ER, Saccone G, Di Mascio D. Exercise during pregnancy risk of preterm birth in overweight and obese women: a systematic review and meta-analysis of randomized controlled trials. *Acta Obstet Gynecol Scand* 2017;215:561–71.
41 Pomeroy J, Renström F, Gradmark AM, *et al*. Maternal physical activity and insulin action in pregnancy and their relationships with infant body composition. *Diabetes Care* 2013;36:267–9.
42 Harrod CS, Chasan-Taber L, Reynolds RM. Physical activity in pregnancy and neonatal body composition: the healthy start study. *Obs Gynecol* 2014;124:257–64.
43 Clapp JF. Influence of endurance exercise and diet on human placental development and fetal growth. *Placenta* 2006;27:527–34.
44 Jackson MR, Gott P, Lye SJ, *et al*. The effects of maternal aerobic exercise on human placental development: placental volumetric composition and surface areas. *Placenta* 1995;16:179–91.
45 The Danish Health Authorities. Recommendations for pregnant women [online], 2014. Available: https://www.sst.dk/en/health-and-lifestyle/physical-activity/recommendations/pregnant-women
46 Broberg L, Ersbøll AS, Backhausen MG, *et al*. Compliance with national recommendations for exercise during early pregnancy in a Danish cohort. *BMC Pregnancy Childbirth* 2015;15:317.
47 Weir Z, Bush J, Robson SC, *et al*. Physical activity in pregnancy: a qualitative study of the beliefs of overweight and obese pregnant women. *BMC Pregnancy Childbirth* 2010;10:1–7.
48 Bauer C, Graf C, Platschek AM. Reasons, motivational factors and percieved personal barriers to engagement in physical activity during pregnancy vary within the bmi classes - the prenatal prevention project Germany. *J Phys Act Heal* 2017;32:1–44.
49 Lindqvist M, Persson M, Mogren I. "Longing for individual recognition" - Pregnant women's experiences of midwives' counselling on physical activity during pregnancy. *Sex Reprod Healthc* 2018;15:46–53.
50 Hawkins M, Chasan-Taber L, Marcus B, *et al*. Impact of an exercise intervention on physical activity during pregnancy: the behaviors affecting baby and you study. *Am J Public Health* 2014;104:e74–81.
51 Oostdam N, van Poppel MNM, Wouters M, *et al*. No effect of the FitFor2 exercise programme on blood glucose, insulin sensitivity, and birthweight in pregnant women who were overweight and at risk for gestational diabetes: results of a randomised controlled trial. *BJOG An Int J Obstet Gynaecol* 2012;119:1098–107.
52 Seneviratne SN, Jiang Y, Derraik JGB, *et al*. Effects of antenatal exercise in overweight and obese pregnant women on maternal and perinatal outcomes: a randomised controlled trial. *BJOG* 2016;123:588–97.
53 Ussher M, Lewis S, Aveyard P, *et al*. Physical activity for smoking cessation in pregnancy: randomised controlled trial. *BMJ* 2015;350:h2145.
54 Gaston A, Prapavessis H. Using a combined protection motivation theory and health action process approach intervention to promote exercise during pregnancy. *J Behav Med* 2014;37:173–84.
55 Vinter CA, Jensen DM, Ovesen P, *et al*. The lip (lifestyle in pregnancy) study: a randomized controlled trial of lifestyle intervention in 360 obese pregnant women. *Diabetes Care* 2011;34:2502–7.
56 Kong KL, Campbell CG, Foster RC, *et al*. A pilot walking program promotes moderate-intensity physical activity during pregnancy. *Med Sci Sports Exerc* 2014;46:462–71.
57 Smith KM. The blossom project online: use of a behaviorally-based website to promote physical activity and prevent excessive gestational weight gain in previously sedentary pregnant women. *ProQuest Dissertations Theses* 2014.
58 Cavalcante SR, Cecatti JG, Pereira RI, *et al*. Water aerobics II: maternal body composition and perinatal outcomes after a program for low risk pregnant women. *Reprod Health* 2009;6:1–7.
59 Haakstad LAH, Bo K. Exercise in pregnant women and birth weight: a randomized controlled trial. *BMC Pregnancy Childbirth* 2011;11:1–7.
60 Tomić V, Sporiš G, Tomić J, *et al*. The effect of maternal exercise during pregnancy on abnormal fetal growth. *Croat Med J* 2013;54:362–8.
61 de Oliveria Melo AS, Silva JLP, Tavares JS, *et al*. Effect of a physical exercise program during pregnancy on uteroplacental and fetal blood flow and fetal growth: a randomized controlled trial. *Obstet Gynecol* 2012;120:302–10.
62 Currie S, Sinclair M, Murphy MH, *et al*. Reducing the decline in physical activity during pregnancy: a systematic review of behaviour change interventions. *PLoS One* 2013;8:e66385.

63 Pearce EE, Evenson KR, Downs DS, *et al*. Strategies to promote physical activity during pregnancy. *Am J Lifestyle Med* 2013;7:38–50.
64 Borg GA. Psychophysical bases of perceived exertion. *Med Sci Sports Exerc* 1982;14:377???381.
65 Miller BG, W. R, Rollnick S. Motivational interviewing: preparing people to change addictive behavior. New York: Guilford press. *J Community Appl Soc Psychol [online]* 1991;2:299–300.
66 Markland D, Ryan RM, Tobin VJ, *et al*. Motivational interviewing and Self–Determination theory. *J Soc Clin Psychol* 2005;24:811–31.
67 Michie S, Ashford S, Sniehotta FF, *et al*. A refined taxonomy of behaviour change techniques to help people change their physical activity and healthy eating behaviours: the CALO-RE taxonomy. *Psychol Health* 2011;26:1479–98.
68 de Vries HJ, Kooiman TJM, van Ittersum MW, *et al*. Do activity monitors increase physical activity in adults with overweight or obesity? A systematic review and meta-analysis. *Obesity* 2016;24:2078–91.
69 Cadmus-Bertram LA, Marcus BH, Patterson RE, *et al*. Randomized trial of a Fitbit-Based physical activity intervention for women. *Am J Prev Med* 2015;49:414–8.
70 Chasan-Taber L, Schmidt MD, Roberts DE, *et al*. Development and validation of a pregnancy physical activity questionnaire. *Med Sci Sports Exerc* 2004;36:1750–60.
71 Santini De Oliveira C, Dos Santos Imakawa T. Physical activity during pregnancy: recommendations and assessment tools. *Rev Bras Ginecol Obs* 2017;39:424–32.
72 Schuster S, Šklempe Kokić I, Sindik J. Measuring physical activity in pregnancy using questionnaires: a meta-analysis. *Acta Clin Croat* 2016;55:440–51.
73 Holmberg Krøner F, de Place Knudsen S, Borup Roland C. Validity and reliability of the Danish version of the pregnancy physical activity questionnaire to assess levels of physical activity during pregnancy, 2020. Journal of Maternal-Fetal and neonatal medicine
74 Abeysekera MV, Morris JA, O'Sullivan AJ. Techniques to measure free-living energy expenditure during pregnancy - A guide for clinicians and researchers. *Obstet Med* 2014;7:60–5.
75 van Hees VT, Renström F, Wright A, *et al*. Estimation of daily energy expenditure in pregnant and non-pregnant women using a wrist-worn tri-axial accelerometer. *PLoS One* 2011;6:e22922–10.
76 Lof M, Forsum E. Activity pattern and energy expenditure due to physical activity before and during pregnancy in healthy Swedish women. *Br J Nutr* 2006;95:296–302.
77 Wong WW, Roberts SB, Racette SB, *et al*. The doubly labeled water method produces highly reproducible longitudinal results in nutrition studies. *J Nutr* 2014;144:777–83.
78 Health Assessment Lab. Medical outcomes trust and QualityMetric incorporated. SF-36v2 health survey 2004.
79 Bjorner JB, Thunedborg K, Kristensen TS, *et al*. The Danish SF-36 Health Survey: Translation and preliminary validity studies. J Clin Epidemiol. 1998;51(11):991–9. 1998:5–10.
80 Jomeen J, Martin CR. The factor structure of the SF-36 in early pregnancy. *J Psychosom Res* 2005;59:131–8.
81 Bland HW, Melton BF, Marshall ES, *et al*. Measuring exercise self-efficacy in pregnant women: psychometric properties of the Pregnancy-Exercise self-efficacy scale (P-ESES). *J Nurs Meas* 2013;21:349–59.
82 Bendix EJ, Holmberg Krøner F, de Place Knudsen S, *et al*. Cross-Cultural adaption, translation and reliability tests of the Danish version of the pregnancy exercise self-efficacy scale. *Sex Reprod Healthc* 2020;26:100542.
83 Mullan E, Markland D, Ingledew DK. A graded conceptualisation of self-determination in the regulation of exercise behaviour: development of a measure using confirmatory factor analytic procedures. In: . 23. Pergamon Person, 1997.
84 Mullan E, Markland D, Mullan E. Variations in Self-Determination across the stages of change for exercise in adults. Vol. 21, motivation and emotion. *Markland & Hardy* 1997.
85 Markland D, Tobin V. A modification to the behavioural regulation in exercise questionnaire to include an assessment of Amotivation. *J Sport Exerc Psychol* 2004;26:191–6.
86 Buysse DJ, Reynolds CF, Monk TH, *et al*. The Pittsburgh sleep quality index: a new instrument for psychiatric practice and research. *Psychiatry Res* 1989;28:193–213.
87 University of Pittsburgh. Pittsburgh sleep quality index (PSQI) 1988;3:6.
88 Qiu C, Gelaye B, Zhong Q-Y, *et al*. Construct validity and factor structure of the Pittsburgh sleep quality index among pregnant women in a Pacific-Northwest cohort. *Sleep Breath* 2016;20:293–301.
89 Cox JL. *Perinatal mental health : a guide to the Edinburgh Postnatal Depression Scale (EPDS). Gaskell*, 2003: 125.
90 Zierau F, Bille A, Rutz W, *et al*. The Gotland male depression scale: a validity study in patients with alcohol use disorder. *Nord J Psychiatry* 2002;56:265–71.
91 Magovcevic M, Addis ME. The masculine depression scale: development and psychometric evaluation. *Psychol Men Masc* 2008;9:117–32.
92 Madsen SA. Spædbarnet i faderens verden (Infants' within the world of the father). *Psyke & Logos [online]* 2008;29:669–87.
93 Craig P. Developing and evaluating complex interventions.
94 Moore G, Audrey S, Barker M, *et al*. Process evaluation in complex public health intervention studies: the need for guidance. *J Epidemiol Community Health* 2014;68:101–2.
95 Hoffmann TC, Erueti C, Glasziou PP. Poor description of non-pharmacological interventions: analysis of consecutive sample of randomised trials. *BMJ* 2013;347:f3755.
96 F. Moore G, Raisanen L, Moore L, *et al*. Mixed-method process evaluation of the Welsh national exercise referral scheme. *Health Educ* 2013;113:476–501.
97 Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM framework, 1999
98 R Core Team. *R: a language and environment for statistical computing*. Vienna, Austria: R Foundation for Statistical Computing, 2020. https://www.r-project.org/
99 Statistical Analysis Plan (SAP) for the FitMum randomized controlled trial [online], 2020. Available: https://clinicaltrials.gov/ProvidedDocs/30/NCT03679130/SAP_000.pdf
100 UK Chief Medical Officers. *Uk chief medical officers recommendations 2017*. Physical Activity in Pregnancy, 2017.
101 UK Chief Medical Officers. UK chief medical officers recommendations 2017: physical activity in pregnancy, guidance 2017:1–7.
102 Verdiere S, Guinhouya BC, Salerno D. Should physical activity be contraindicated during pregnancy in relation to its potentially related risks? 2017;45:104–11.
103 Melo A, Silva JLP, Tavares JS. Effect of a physical exercise program during pregnancy on Uteroplacental and fetal blood flow and fetal growth 2012;120:302–10.
104 RÃªgo AS, Alves MTSSdeBe, Batista RFL. Physical activity in pregnancy and adverse birth outcomes 2016;32:1–10.
105 Charlesworth S, Foulds HJ, Burr J, *et al*. Evidence-based risk assessment and recommendations for physical activity clearance: pregnancy. *Appl Physiol Nutr Metab* 2011;36:S154–89.
106 Brickwood K-J, Watson G, O'Brien J, *et al*. Consumer-based wearable activity trackers increase physical activity participation: systematic review and meta-analysis. *JMIR Mhealth Uhealth* 2019;7:e11819.
107 Wright SP, Hall Brown TS, Collier SR, *et al*. How consumer physical activity monitors could transform human physiology research. *Am J Physiol Regul Integr Comp Physiol* 2017;312:R358–67.
108 Guérin E, Ferraro ZM, Adamo KB, *et al*. The need to objectively measure physical activity during pregnancy: considerations for clinical research and public health impact. *Matern Child Health J* 2018;22:637–41.
109 Grym K, Niela-Vilén H, Ekholm E, *et al*. Feasibility of smart wristbands for continuous monitoring during pregnancy and one month after birth. *BMC Pregnancy Childbirth* 2019;19:1–9.
110 Wear and care tips for garmin watches [online]. Available: https://support.garmin.com/en-US/?faq=yAgOpDYLCe4ftSa9k0dQx7&searchType=noProduct&sas_source=grmn [Accessed 8 Sep 2019].

Paper 2

Effects of structured supervised exercise training or motivational counseling on pregnant women's physical activity level: FitMum - a randomized controlled trial

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Abstract

Background

Physical activity (PA) during pregnancy is an effective and safe way to improve maternal health in uncomplicated pregnancies. However, compliance with physical activity recommendations remains low among pregnant women. Although many exercise intervention studies in pregnant women have been conducted, there is a need to investigate the effect of interventions on actual PA levels. Implementing different strategies to increase PA during pregnancy that incorporate novel health technology to measure and increase PA is warranted.

Objectives

The purpose of this study is to evaluate the effects of offering structured supervised exercise training (EXE) or motivational counseling (MOT) during pregnancy on moderate-to-vigorous-intensity physical activity (MVPA) level. Additionally, we investigated complementary measures of physical activity by the Pregnancy Physical Activity Questionnaire (PPAQ) and 'gold standard' doubly labeled water (DLW).

Methods

A randomized controlled trial included 220 healthy, inactive pregnant women with a median gestational age of 12.9 (interquartile range, 9.4-13.9) weeks. 219 women were randomised to standard care (CON) (n=45), EXE (n=87), or MOT (n=87). The primary outcome was MVPA (min/week) from randomization to the 29th gestational week obtained by a wrist-worn commercial activity tracker (Garmin Vivosport). Moreover, PA was measured by the activity tracker throughout pregnancy, by PPAQ and DLW. The primary outcome analysis was performed as an ANCOVA model adjusting for baseline PA.

Results

The average MVPA (min/week) from randomization to the 29th gestational week was 33 [95%

confidence interval, 18;47] in CON, 50 [39;60] in EXE and 40 [30;51] in MOT. When adjusted for baseline MVPA, participants in EXE performed 20 [4;36] min/week more MVPA than participants in CON (*P*=.016). MOT was not more effective than CON, and EXE and MOT also did not differ. MVPA was positively associated with the number of exercise sessions attended in EXE from randomization to delivery (*P*=.038). Attendance was higher for online (due to COVID-19 restrictions) compared to physical exercise training (*P*=.027). Adverse events and serious adverse events did not differ between groups.

Conclusions

Offering structured supervised exercise training was more effective than standard care to increase MVPA among pregnant women, whereas offering motivational counseling on PA was not. MVPA in the intervention groups did not reach the recommended level in pregnancy. Altering the intervention into online due to COVID-19 restrictions did not affect MVPA level but increased exercise participation.

Trial registration

The study is registered at clinicaltrials.gov (NCT03679130).

Keywords

Physical activity; pregnancy; randomized controlled trial; interventions; commercial activity tracker; COVID-19; maternal health; doubly labeled water; pregnancy physical activity questionnaire

Introduction

Physical activity (PA) is a safe and effective way to improve maternal health in uncomplicated pregnancies (1,2). Regular PA during pregnancy reduces the risk of gestational weight gain, gestational diabetes mellitus, gestational hypertension, pre-eclampsia, cesarean section (3), and depression (4). In addition, lifestyle interventions during pregnancy may improve offspring health by improving placental function (5,6), reducing the risk of preterm delivery (3), and normalizing birth weight (7,8). Nevertheless, compliance with PA recommendations remains low among pregnant women worldwide (9). Therefore, a pressing issue to address is how to implement PA in everyday life of pregnant women.

A diverse range of approaches to PA interventions exists, of which structured supervised exercise training or motivational counseling strategies, respectively, are used widely in the literature (10). Supervised exercise training with scheduled exercise sessions provides a standard approach to increase PA in pregnant women. Recognizing the needs of an individually tailored approach (11,12), motivational counseling focuses on PA behavior and has also been shown to reduce the decline or even increase PA during pregnancy (13–15). Structured supervised exercise training or motivational counseling on PA have been applied separately in studies of pregnant women (16,17,26,18–25), but a direct comparison of the two approaches to increase PA during pregnancy has not yet been performed.

The primary objective of FitMum was to evaluate the effects of offering structured supervised exercise training (EXE) or motivational counseling on PA (MOT) compared to standard care (CON) on moderate-to-vigorous-intensity PA (MVPA) in pregnant women as determined by a wrist-worn commercial activity tracker. Secondary measures of PA were obtained by the Danish version of the "Pregnancy Physical Activity Questionnaire" (PPAQ-DK) (27,28) and by the "gold-

standard" doubly labeled water technique (DLW) (29–31). The hypotheses were that both EXE and MOT would increase MVPA in pregnancy compared to CON, and that EXE would be more effective than MOT (32,33). In addition, the association between MVPA and the number of sessions attended was explored.

Methods

Patient and public involvement

The development of FitMum was inspired by stakeholders; 27 semi-structured interviews with Danish pregnant women, midwives and obstetricians were performed to explore the feasibility, facilitators, and barriers to PA during pregnancy.

Participants and trial design

FitMum was a single-site randomized controlled trial (RCT) conducted in 2018-2021 at the Department of Gynaecology and Obstetrics at Nordsjaellands Hospital, Hillerod, Denmark (32). 220 healthy, inactive pregnant women with a gestational age (GA) of ≤15 weeks and 0 days were included (visit 1). Participants were randomized 1:2:2 into CON, EXE, and MOT groups, respectively (Figure 1).

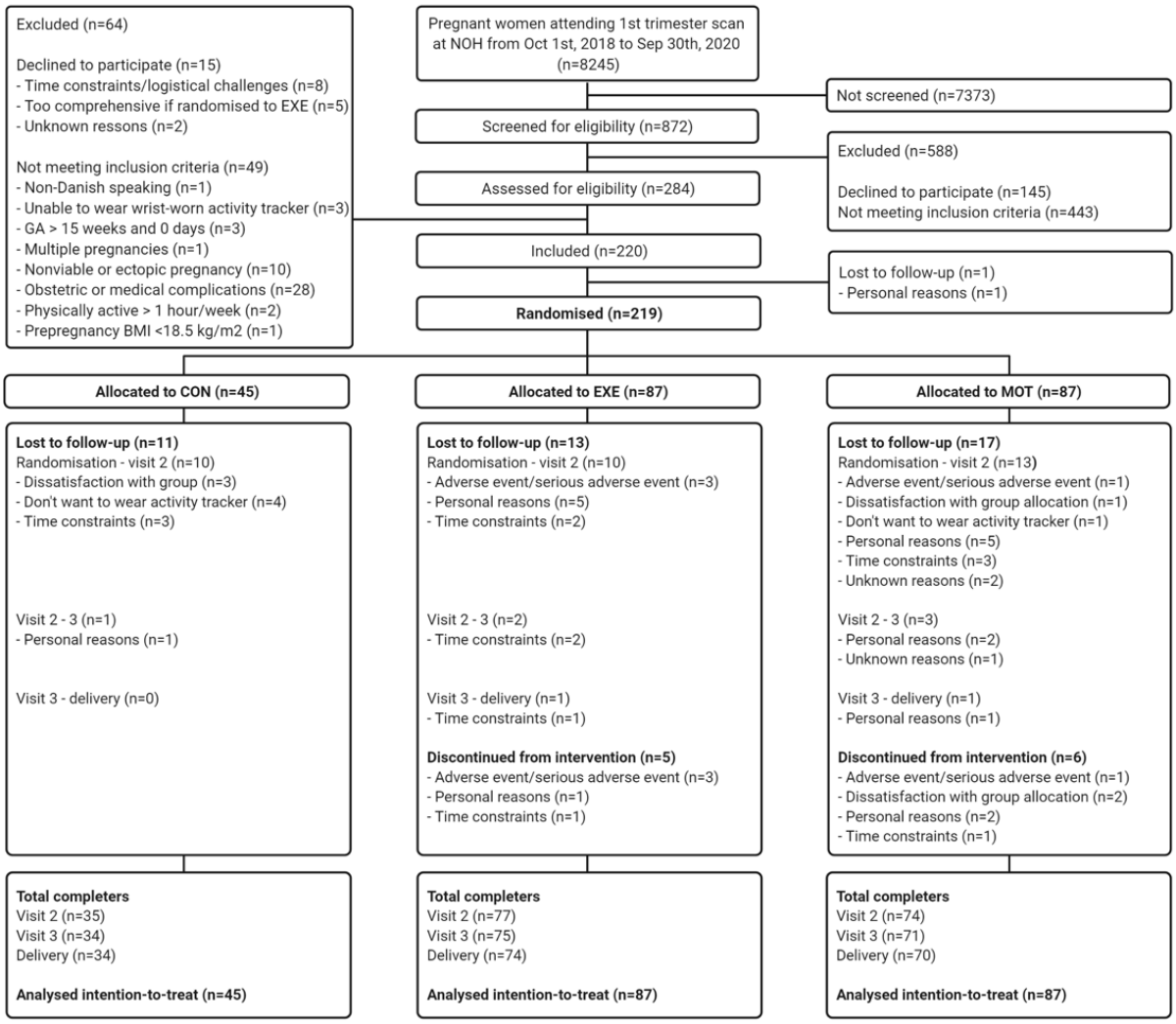


Figure 1: Flowchart of the FitMum randomised controlled trial including enrolment, study group allocation, follow-up, and data analysis. Visit 1, inclusion at gestational age (GA) of maximum 15 weeks and 0 days; randomisation at GA of maximum 16 weeks and 0 days; visit 2, the 29th week of gestation; visit 3, the 35th week of gestation; CON, standard care; EXE, structured supervised exercise training; MOT, motivational counselling on physical activity.
The figure is created with Biorender.com

Participants were invited to a test visit at 29th gestational week (visit 2) and at 35th gestational week (visit 3).

Interventions

All three groups were offered standard care. In addition, EXE was offered one-hour group-based supervised exercise training at moderate intensity three times/week in a gym and swimming pool. MOT was offered four individual and three group PA motivational counseling face-to-face sessions of 1-2 hours duration during pregnancy and one weekly, personalized SMS to support PA. Interventions ran from randomization until delivery. The target PA level for EXE and MOT was at least 30 min/day at a moderate intensity as recommended in Denmark to healthy pregnant women (34). The interventions were converted into online versions during the COVID-19 pandemic restrictions that were introduced in Denmark on March 11th, 2020, and throughout the study period. EXE could access to the swimming pool for three months during this period.

Outcome measures

The data collection procedures are illustrated in Figure 2.

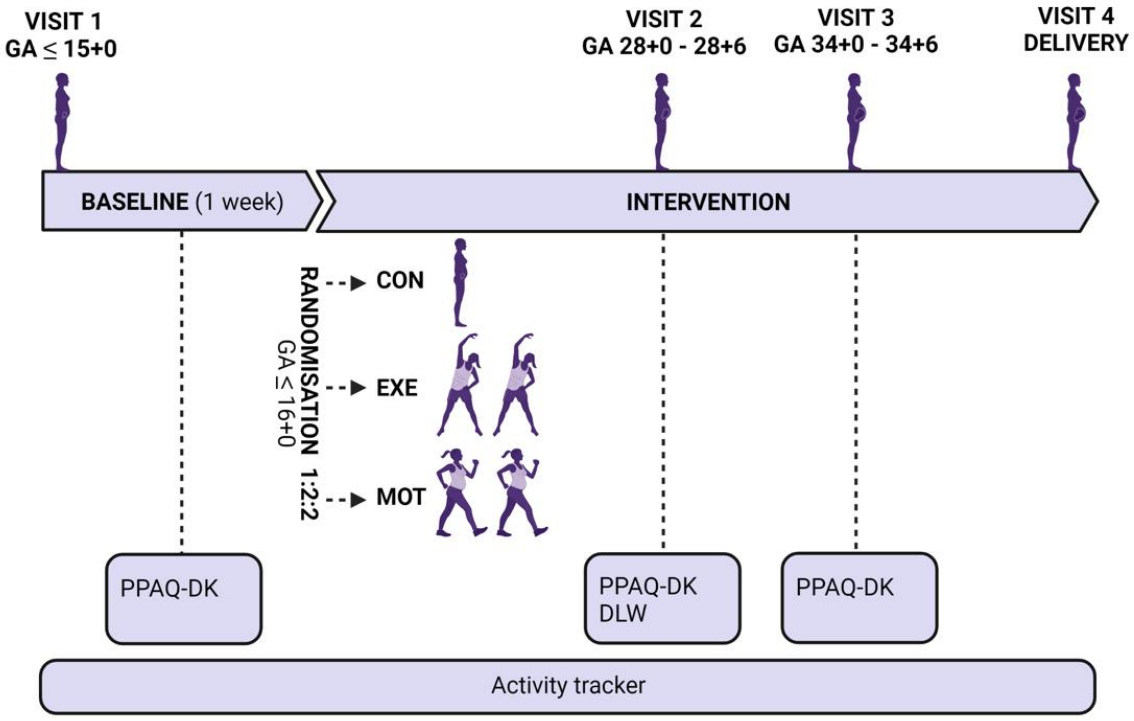


Figure 2: Before the COVID-19 pandemic, visits were held at the hospital. During the COVID-19, visits were periodically held online. PPAQ-DK, Danish version of Pregnancy Physical Activity Questionnaire; DLW, doubly labelled water; GA, gestational age; CON, standard care; EXE, structured supervised exercise training; MOT, motivational counselling on physical activity. The figure is created with Biorender.com

Activity tracker

The primary outcome was MVPA (min/week) from randomization to visit 2. PA was continuously captured by a wrist-worn commercial activity tracker (Garmin Vivosport) (35) with a built-in heart rate monitor and accelerometer from inclusion to delivery. Baseline PA was captured from inclusion to randomization (six full days). PA with a Metabolic Equivalent of Task (MET) value of ≥3 in bouts of at least ten consecutive minutes was recorded as MVPA by the activity tracker (35). Secondary outcomes measured by the activity tracker were PA duration at a moderate and vigorous intensity, respectively, steps, active time, active kilocalories, floors climbed, and minimum, maximum, resting, and average heart rate from randomization to delivery. At inclusion, the activity tracker was pre-set with turned off PA notifications and an identical face of the tracker showing only clock and battery level. After randomization, women in MOT were encouraged to personalize the tracker with e.g. individual goal settings and PA notifications as part of the intervention. Throughout the study period tracker software was automatically updated (35).

Pregnancy Physical Activity Questionnaire

PA was digitally self-reported by participants using PPAQ-DK (28) at visit 1, 2 and 3, respectively. The questionnaire assesses PA related to everyday activities during the current trimester, including e.g. household, occupational, sports, and transportation (27).

Doubly labeled water

Participants collected two baseline urine samples prior to test visit 2, drank the DLW dose at the

visit followed by five post-dose urine samples at home on days one, four, seven, 11 and 14 (31,36). The calculation of total energy expenditure (TEE) was based on the Weir equation (36), and the active energy expenditure (AEE) was calculated by subtracting the basal metabolic rate (BMR) from TEE. BMR was estimated by an equation appropriate for pregnant women (37). PA level (PAL) was calculated by dividing TEE by BMR.

Activity tracker data management

PA was transferred via Bluetooth from the activity tracker to the Garmin Connect app (Garmin International) (35) from which Fitabase (Small Steps Labs LLC) obtained the data via the programming interface. PA was monitored through Fitabase and participants were reminded if the activity trackers were not synchronizing. PA data were downloaded from Fitabase, processed, and cleaned in the software R (38).

Statistical analyses

Statistical analyses were performed according to our statistical analysis plan (33) using R (38). Data are presented as means ± standard deviation for symmetric distributions, medians and interquartile ranges for skewed data, and categorical variables are presented as frequency (%). The level of statistical significance was 5%, except for the primary hypothesis where each of the two comparisons was tested at the 2.5% level. Wald-based 95% confidence intervals (CI) were given for all reported estimates (33).

Intention-to-treat analyses using all randomized participants were performed for the primary outcome. Missing observations in tracker data due to non-wear time were imputed by multiple imputations in 25 data sets using a pre-specified seed, pre-selected baseline variables (body weight, age, PA, educational level, and parity), and the random forest imputation model from the mice R package (39). A statistician blinded for the intervention performed the imputation and the primary

outcome analysis as an ANCOVA model adjusting for baseline PA. MVPA before and during the COVID-19 pandemic was compared within groups with a linear regression model. Cumulative trajectories were estimated from the imputed data using a generalized additive model with a penalized regression spline with point-wise 95% confidence bands estimated by a bootstrap procedure (40).

For the PPAQ-DK outcome, a constrained linear mixed model was fitted with the observation times as a factor (41). Both within and between-group effects were reported as estimated differences in means.

For the DLW outcome, a one-way ANOVA was used to compare the three group averages.

Linear regression was used to model the relationship between attended intervention sessions and attained MVPA in EXE and MOT.

Results

Participants and adherence to interventions

In total, 220 pregnant women were included from October 2018 to October 2020. Of those, 219 were randomly allocated to CON (n=45), EXE (n=87) or MOT (n=87) (Figure 1). Maternal baseline characteristics are presented in Table 1.

Baseline characteristics	ALL	CON	EXE	MOT
	n=219	n=45	n=87	n=87
Age (years), mean (SD)	31.5 (4.3)	32.0 (4.6)	31.1 (4.3)	31.7 (4.1)
Gestational age at inclusion (weeks), median (IQR)	12.9 (9.4-13.9)	12.9 (9.7-13.9)	12.6 (9.3-13.7)	12.9 (9.6-13.9)
Weight (kg), mean (SD)	75.4 (15.3)	72.0 (13.7)	76.2 (17.4)	76.3 (13.8)
Prepregnancy BMI (kg/m^2)*, median (IQR)	24.1 (21.8-28.7)	23.5 (21.3-26.8)	25.2 (21.6-29.8)	24.1 (22.4-28.9)
Nulliparity, n (%)	82 (37)	16 (36)	40 (46)	26 (30)
Educational level, n (%)				
School ≥12 years	191 (87)	41 (91)	74 (85)	76 (87)
Further education ≥3 years	175 (80)	33 (73)	73 (84)	69 (79)
Employed/studying, n (%)	199 (91)	39 (87)	83 (95)	77 (89)
Smoking during pregnancy, n (%)	2 (1)	0 (0)	1 (1)	1 (1)

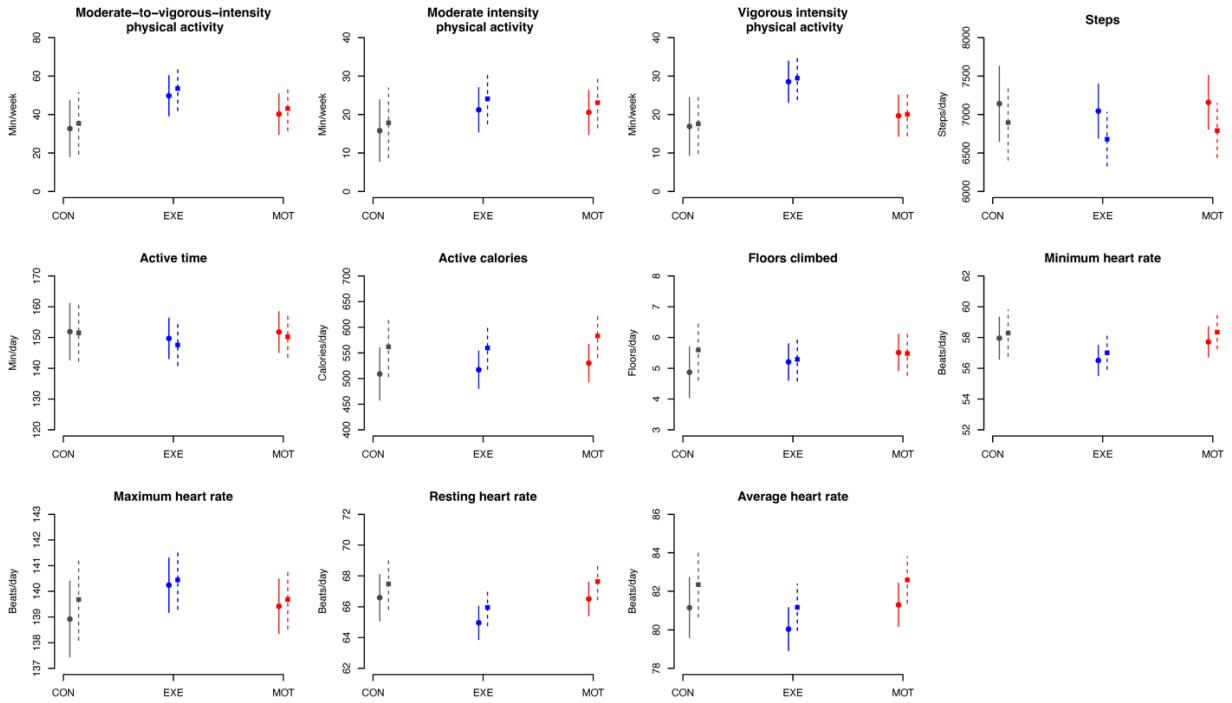
Table 1: Baseline characteristics of randomised participants. Descriptive data are presented as means ± SD for symmetrically distributions, medians (IQR) skewed data, and n (%). *Prepregnancy body mass index (BMI) is calculated based on n=218 (CON: n=45, EXE: n=86, MOT: n=87) due to a missing value. School ≥12 years corresponds to high school. Further education ≥3 years corresponds to a university degree (bachelor or master level). SD, Standard deviation; IQR, interquartile range; CON, standard care; EXE, structured supervised exercise training; MOT, motivational counselling on physical activity.

From randomisation to visit 2, 15% of the participants were lost to follow-up (CON: n=10 (22%); EXE: n=10 (11%); MOT: n=13 (15%)). The main reason (n=18 (55%)) was personal matters, e.g., time consumed on participation or family reasons. From randomization to delivery, 19% of the participants were lost to follow-up, and proportions were similar across groups (Figure 1). Participants randomized to EXE participated in 1.4 [95% CI, 1.2;1.6] exercise session/week from randomization to visit 2, and 1.3 [1.1;1.5] exercise session/week from randomization to delivery. Participants randomized to MOT joined 5.2 [4.7;5.7] counseling sessions during their pregnancy.

Physical activity by the activity tracker

Moderate-to-vigorous-intensity physical activity

The average MVPA (min/week) from randomisation to visit 2 was 33 [18;47] in CON, 50 [39;60] in EXE and 40 [30;51] in MOT (Figure 3).



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216 Figure 3: Average and 95% CI of moderate-to-vigorous-intensity physical activity (MVPA) and complementary tracker
217 outcomes from randomisation to visit 2 (the 29th week of gestation) (full line) and delivery (dotted line), respectively.
218 MVPA was continuously captured by a wrist-worn commercial activity tracker (Garmin Vivosport) with a built-in heart
219 rate monitor and accelerometer. Age, sex, weight and height were entered in the Garmin app. MVPA, sum of
220 moderate and vigorous intensity physical activity (PA) in min/week; moderate intensity PA, cumulative duration of
221 activities of moderate-intensity (MET=3-6) lasting at least 10 consecutive min in min/week; vigorous intensity PA,
222 cumulative duration of activities of vigorous-intensity (MET>6) lasting at least 10 consecutive min in min/week; steps,
223 steps counted per day; active time, active time in min/day; active kilocalories (Kcal), calories burned through actual
224 movement in Kcal/day; floors climbed, number of floors climbed per day (a floor climbed is equal to 3 meters);
225 minimum heart rate, the lowest heart rate in beats/min; maximum heart rate, the highest heart rate in beats/min;
226 resting heart rate, the average of seven days of the resting heart rate in beats/min; average heart rate, the average
227 heart rate in beats/min; CI, confidence interval; CON,s; EXE, structured supervised exercise training; MOT,
228 motivational counselling on physical activity.

229

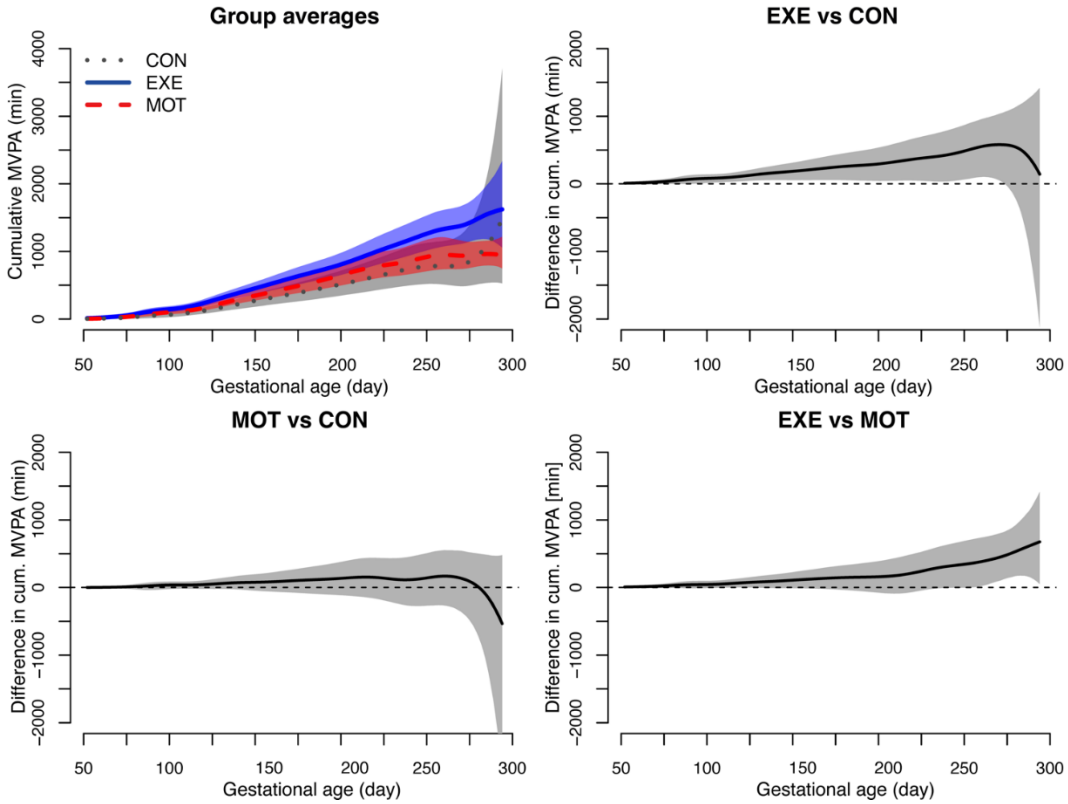
When adjusted for baseline MVPA, participants in EXE performed 20 [4;36] min/week more MVPA than participants in CON (*P*=.016) (Table 2).

	CON vs EXE				CON vs MOT				MOT vs EXE			
	Visit 2		Delivery		Visit 2		Delivery		Visit 2		Delivery	
	Differences [95% CI]	p-value	Differences [95% CI]	p-value	Differences [95% CI]	p-value	Differences [95% CI]	p-value	Differences [95% CI]	p-value	Differences [95% CI]	p-value
MVPA (min/week)	20 [4;36]	0.016*	21 [3;39]	0.022*	10 [-6;26]	0.231	10 [-8;28]	0.267	10 [-3;24]	0.137	11 [-4;26]	0.147
Moderate intensity (min/week)	5 [-3;13]	0.223	6 [-4;16]	0.235	3 [-5;11]	0.453	4 [-6;13]	0.468	2 [-5;9]	0.571	2 [-6;10]	0.575
Vigorous intensity (min/week)	13 [4;22]	0.007*	13 [3;22]	0.009*	4 [-5;13]	0.392	3 [-6;13]	0.474	9 [1;16]	0.024*	9 [1;17]	0.020*
Steps (steps/day)	251 [-173;674]	0.245	136 [-274;546]	0.513	149 [-272;571]	0.486	32 [-375;440]	0.876	102 [-246;449]	0.566	104 [-233;441]	0.544
Active time (min/day)	4 [-4;12]	0.301	3 [-5;10]	0.497	4 [-4;12]	0.357	3 [-5;11]	0.482	0.5 [-6;7]	0.886	0.1 [-6;6]	0.980
Active kilocalories (kcal/day)	25 [-15;64]	0.224	15 [-32;62]	0.523	29 [-10;69]	0.148	30 [-17;77]	0.204	-5 [-37;28]	0.779	-15 [-53;24]	0.444
Floors climbed (floors/day)	1 [-0.2;1]	0.161	-0.1 [-1;1]	0.839	1 [-0.1;1]	0.071	-0.1 [-1;1]	0.907	-0.2 [-1;0.5]	0.620	-0.04 [-1;1]	0.917
Minimum heart rate (beats/min)	-0.5 [-1;1]	0.263	-0.3 [-1;1]	0.616	0.1 [-1;1]	0.857	-0.4 [-1;1]	0.418	-1 [-1;0.1]	0.116	-1 [-2;0.1]	0.114
Maximum heart rate (beats/min)	2 [0.3;3]	0.021*	1 [-0.4;3]	0.144	1 [-1;2]	0.266	0.3 [-1;2]	0.680	1 [0;2]	0.139	1 [-0.4;2]	0.204
Resting heart rate (beats/min)	-0.2 [-1;1]	0.628	-0.02 [-1;1]	0.968	0.3 [-1;1]	0.516	1 [-0.5;2]	0.284	-1 [-1;0.2]	0.172	-1 [-1;0.3]	0.181
Average heart rate (beats/min)	0.03 [-1;1]	0.941	0.02 [-1;1]	0.975	0.5 [-0.4;1]	0.259	1 [0.4;2]	0.220	-0.5 [-1;0.3]	0.203	-1 [-1;0.2]	0.149

Table 2: Comparison between groups based on imputed activity tracker datasets (intention to treat analysis) from randomisation to visit 2 and delivery, respectively. A positive mean value indicates that the last-mentioned group has the highest mean. MVPA, sum of moderate and vigorous intensity physical activity (PA) in min/week; moderate intensity PA, cumulative duration of activities of moderate-intensity (MET=3-6) lasting at least 10 consecutive min in min/week; vigorous intensity PA, cumulative duration of activities of vigorous-intensity (MET> 6) lasting at least 10 consecutive min in min/week; steps, steps counted per day; active time, active time in min/day; active kilocalories (Kcal), calories burned through actual movement in Kcal/day; floors climbed, number of floors climbed per day (a floor climbed is equal to 3 meters); minimum heart rate, the lowest heart rate in beats/min; maximum heart rate, the highest heart rate in beats/min; resting heart rate, the average of seven days of the resting heart rate in beats/min; average heart rate, the average heart rate in beats/min; visit 2, the 29th gestational week.*Significant difference. CI, confidence interval; CON, standard care; EXE, structured supervised exercise training; MOT, motivational counseling on physical activity.

The same pattern was seen throughout the entire pregnancy, hence the unadjusted average MVPA (min/week) was 35 [19;51] in CON, 54 [42;65] in EXE and 43 [32;55] in MOT from randomization to delivery (Figure 3). Throughout pregnancy participants in EXE performed 21 [3;39] min/week more MVPA than participants in CON when adjusted for baseline MVPA (*P*=.022) (Table 2). There were no significant differences in adjusted MVPA between CON and MOT (randomization to visit 2: *P*=.231; randomization to delivery: *P*=.267) or between MOT and EXE (randomization to visit 2: *P*=.137; randomization to delivery: *P*=.147) (Table 2).

Unplanned analysis on cumulative MVPA from randomization to delivery revealed that EXE tended to have more MVPA compared to MOT, which became significant in the late part of pregnancy (Figure 4 and 5).



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257 Figure 4: Cumulative moderate-to-vigorous-intensity physical activity (MVPA) from randomisation to delivery. MVPA was
258 continuously captured by a wrist-worn commercial activity tracker (Garmin Vivosport) with a built-in heart rate monitor and
259 accelerometer. Age, sex, weight and height were entered in the Garmin app. EXE vs CON, MOT vs CON, EXE vs MOT: the black
260 line shows the MVPA difference in min between groups for each gestational age in days, the grey area shows the 95% CI. CI,
261 confidence interval; CON, standard care; EXE, structured supervised exercise training; MOT, motivational counselling on physical
262 activity.

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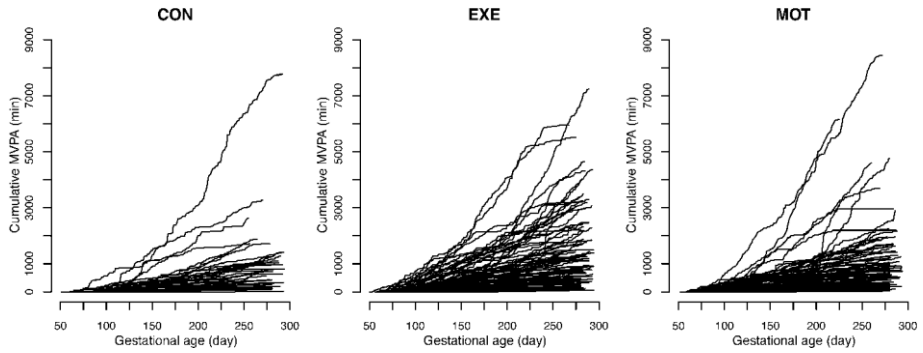

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Figure 5: Individual cumulative moderate-to-vigorous-intensity physical activity (MVPA) from randomisation to delivery in CON, EXE and MOT. MVPA was continuously captured by a wrist-worn commercial activity tracker (Garmin Vivosport) with a built-in heart rate monitor and accelerometer. Age, sex, weight and height were entered in the Garmin app. CON, standard care; EXE, structured supervised exercise training; MOT, motivational counselling on physical activity.

The same tendency was seen between CON and EXE, but the difference was insignificant. Cumulative MVPA did not differ between CON and MOT.

COVID-19 sensitivity analysis

MVPA (min/week) did not differ between participants included before the COVID-19 pandemic (physical intervention only, n=120) and during the COVID-19 pandemic (online intervention only, n=63) in either CON (-14 [-49;22], *P*=.444), EXE (-16 [-42;11], *P*=.251), or MOT (-6 [-37;25], *P*=.712) (Figure 6).

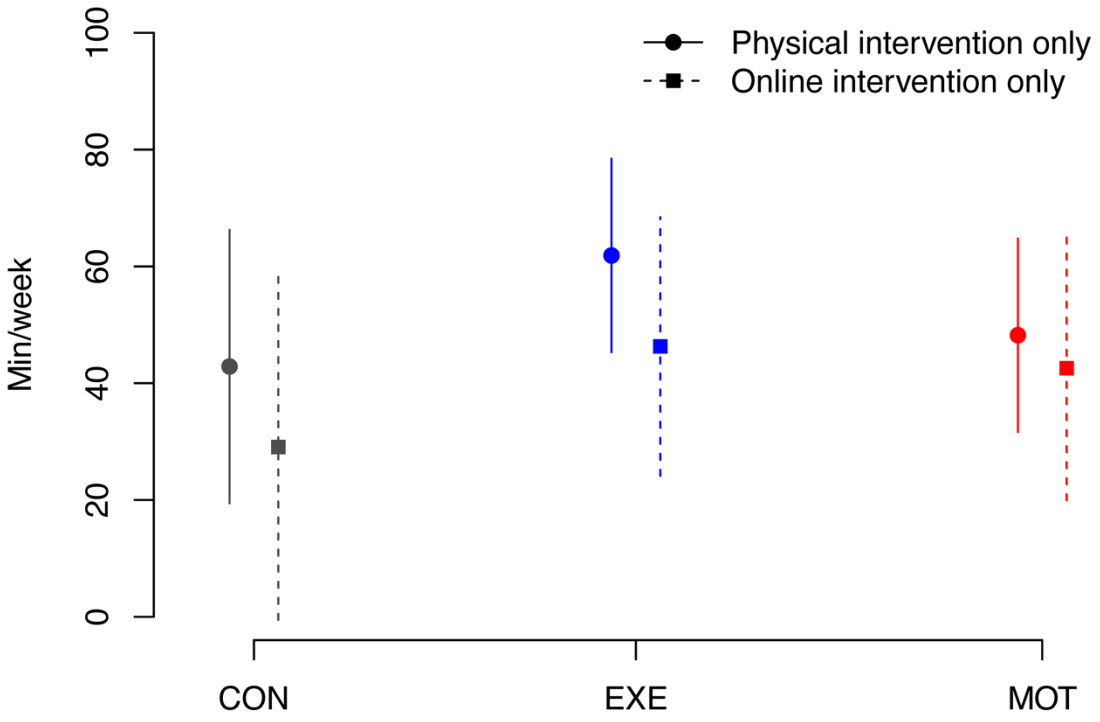


Figure 6: Average and 95% CI of moderate-to-vigorous-intensity physical activity (MVPA) in min/week. MVPA was continuously captured by a wrist-worn commercial activity tracker (Garmin Vivosport) with a built-in heart rate monitor and accelerometer. Age,

sex, weight and height were entered in the Garmin app. The COVID-19 pandemic restrictions started March 11th, 2020. Physical intervention, participants (n=120) started and finished the intervention before COVID-19; online intervention, participants (n=63) started and finished the intervention during COVID-19. CI, confidence interval; CON, standard care; EXE, structured supervised exercise training; MOT, motivational counselling on physical activity.

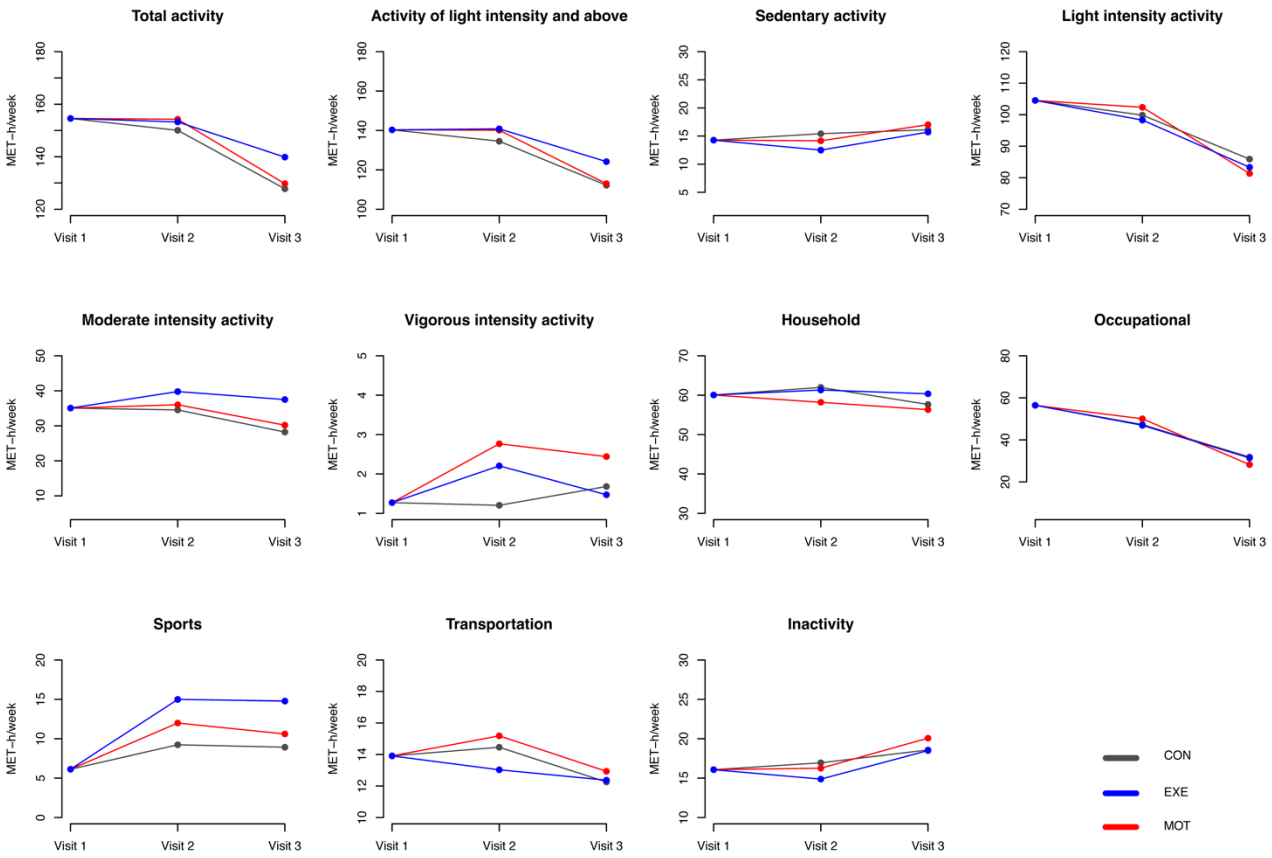
Women in EXE offered the online intervention only, participated in more exercise sessions/week than women offered the physical intervention only (online: 1.6 [1.3;2.0], physical: 1.1 [0.9;1.4], *P*=.027). Participants in EXE attended on average 4.9 swimming pool sessions in the online intervention period. The number of MOT sessions attended did not differ between women who were offered the intervention before or during the COVID-19 pandemic (physical: 5.3 [4.6;6.0], online: 5.6 [4.8;6.4], *P*=.970). Participants included before the COVID-19 pandemic and delivered during (n=36) were excluded in this analysis based on their mixed intervention.

Secondary activity tracker outcomes

All tracker outcomes are presented in Figure 2 and accompanying statistics in Table 2. PA at a vigorous intensity (min/week) was higher in EXE than in both CON and MOT (CON vs. EXE: randomization to visit 2: 13, randomization to delivery: 13 [4;22]; MOT vs. EXE: randomization to visit 2: 9 [1;16], randomization to delivery: 9 [1;17]). In addition, the maximum heart rate was 2 [0.3;3] beats/min higher in EXE compared to CON from randomization to visit 2. No other tracker outcomes differed between groups.

Physical activity by Pregnancy Physical Activity Questionnaire

PPAQ-DK was completed by 219 (100%), 182 (83%) and 169 (77%) participants, respectively, at visit 1, 2 and 3, respectively. Figure 7 shows the PA behaviors categorized by intensity and type. Differences between and within groups are shown in Table 3 and 4.



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304 Figure 7: Baseline-constrained comparison between groups based on the means of physical activity level from the Danish version of
305 the Pregnancy Physical Activity Questionnaire (PPAQ-DK). Visit 1, gestational age of maximum 15 weeks and 0 days; visit 2, the
306 29th gestational week; visit 3, the 35th gestational week; MET, metabolic equivalent of task; h/week, hours/week; CON, standard
307 care; EXE, structured supervised exercise training; MOT, motivational counselling on physical activity.

308

	CON vs EXE				CON vs MOT				MOT vs EXE			
	Visit 2		Visit 3		Visit 2		Visit 3		Visit 2		Visit 3	
	Differences [95% CI]	p-value	Differences [95% CI]	p-value	Differences [95% CI]	p-value	Differences [95% CI]	p-value	Differences [95% CI]	p-value	Differences [95% CI]	p-value
Total activity (MET-h/week)												
Total activity	3 [-13;19]	0.695	12 [-8;32]	0.230	4 [-12;20]	0.609	2 [-18;22]	0.851	-1 [-14;12]	0.876	10 [-6;26]	0.207
Activity of ≥ light intensity	6 [-10;23]	0.453	12 [-7;31]	0.226	6 [-11;22]	0.510	1 [-19;21]	0.938	1 [-13;14]	0.917	11 [-4;27]	0.157
Intensity (MET-h/week)												
Sedentary	-3 [-6;1]	0.095	-0.4 [-5;4]	0.842	-1 [-5;2]	0.474	2 [-3;5]	0.684	-2 [-4;1]	0.242	-1 [-5;2]	0.444
Light	-2 [-13;10]	0.795	6 [-17;12]	0.226	2 [-9;14]	0.685	6 [-19;10]	0.542	-4 [-14;6]	0.406	2 [-10;13]	0.735
Moderate	5 [-4;14]	0.257	9 [-2;21]	0.108	1 [-8;11]	0.751	2 [-10;13]	0.741	4 [-4;11]	0.314	7 [-2;16]	0.112
Vigorous	1 [-1;3]	0.233	-0.2 [-2;2]	0.815	2 [0;3]	0.657	1 [-1;3]	0.408	-1 [-2;1]	0.407	-1 [-2;0.4]	0.177
Type (MET-h/week)												
Household	-1 [-10;9]	0.891	3 [-9;14]	0.652	-4 [-13;6]	0.433	-1 [-13;11]	0.829	3 [-4;11]	0.417	4 [-5;13]	0.401
Occupational	-0.4 [-13;12]	0.955	-0.4 [-15;15]	0.958	3 [-10;15]	0.662	-4 [-19;12]	0.647	-3 [-13;7]	0.538	3 [-9;15]	0.604
Sports	6 [-1;6]	0.001*	6 [2;10]	0.003*	3 [-1;6]	0.121	2 [-2;6]	0.396	3 [0.2;6]	0.036*	4 [1;7]	0.008*
Transportation	-1 [-5;3]	0.485	0.1 [-4;4]	0.954	1 [-3;5]	0.726	1 [-3;5]	0.733	-2 [-5;1]	0.193	-1 [-4;2]	0.717
Inactivity	-2 [-6;2]	0.261	-0.1 [-5;5]	0.975	-1 [-4;3]	0.713	2 [-3;6]	0.539	-1 [-4;2]	0.353	-2 [-5;2]	0.410

Table 3. Comparison between groups based on physical activity level from the Danish version of the Pregnancy Physical Activity Questionnaire (PPAQ-DK). A positive mean value indicates that the last-mentioned group has the highest mean. Visit 2, the 29th gestational week; visit 3, the 29th gestational week. *Significant difference. CI, confidence interval; MET, metabolic equivalent of task; h/week, hours/week; CON, standard care; EXE, structured supervised exercise training; MOT, motivational counseling on physical activity.

	CON					EXE					MOT				
	Visit 1	**Visit 2**	**Visit 3**	**Time effect from visit 1 - visit 2 (p-value)**	**Time effect from visit 1 - visit 3 (p-value)**	**Visit 1**	**Visit 2**	**Visit 3**	**Time effect from visit 1 - visit 2 (p-value)**	**Time effect from visit 1 - visit 3 (p-value)**	**Visit 1**	**Visit 2**	**Visit 3**	**Time effect from visit 1 - visit 2 (p-value)**	**Time effect from visit 1 - visit 3 (p-value)**
	n=45	**n=35**	**n=31**			**n=87**	**n=76**	**n=74**			**n=87**	**n=71**	**n=64**		
	Mean ± SD					Mean ± SD					Mean ± SD				
Total activity (MET-h/week)															
Total activity	161 ± 43	154 ± 44	132 ± 52	-7 (0.344)	-29 (0.001)*	150 ± 49	151 ± 50	136 ± 56	1 (0.881)	-14 (0.048)*	157 ± 52	155 ± 52	127 ± 45	-2 (0.830)	-30 (<0.001)*
Activity of ≥ light intensity	147 ± 44	139 ± 44	117 ± 50	-8 (0.250)	-30 (<0.001)*	135 ± 48	138 ± 49	121 ± 54	3 (0.590)	-14 (0.032)*	142 ± 50	140 ± 55	112 ± 47	-2 (0.854)	-30 (<0.001)*
Intensity (MET-h/week)															
Sedentary	13 ± 10	15 ± 13	15 ± 12	2 (0.316)	2 (0.245)	15 ± 12	12 ± 8	15 ± 12	3 (0.072)	0 (0.311)	14 ± 14	14 ± 14	16 ± 14	0 (0.923)	2 (0.036)*
Light	112 ± 35	106 ± 34	91 ± 45	-6 (0.158)	-21 (<0.001)*	98 ± 34	96 ± 33	81 ± 34	-2 (0.348)	-17 (<0.001)*	108 ± 37	104 ± 41	82 ± 34	-4 (0.376)	-26 (<0.001)*
Moderate	33 ± 21	32 ± 21	26 ± 20	-1 (0.914)	-7 (0.297)	36 ± 30	40 ± 29	37 ± 36	4 (0.172)	1 (0.631)	35 ± 27	35 ± 25	29 ± 22	0 (0.735)	-6 (0.21)
Vigorous	1 ± 3	1 ± 2	2 ± 5	0 (0.972)	1 (0.562)	1 ± 3	2 ± 4	2 ± 3	1 (0.089)	1 (0.885)	1 ± 2	3 ± 5	2 ± 5	2 (0.002)*	1 (0.026)*
Type (MET-h/week)															
Household	65 ± 36	63 ± 35	59 ± 31	-2 (0.844)	-6 (0.423)	54 ± 34	57 ± 39	56 ± 35	3 (0.349)	2 (0.432)	64 ± 44	60 ± 39	57 ± 36	-4 (0.363)	-7 (0.181)
Occupational	56 ± 29	49 ± 29	34 ± 32	-7 (0.128)	-22 (<0.001)*	57 ± 37	47 ± 36	31 ± 42	-10 (0.021)*	-26 (<0.001)*	56 ± 32	50 ± 31	28 ± 30	-6 (0.143)	-28 (<0.001)*
Sports	7 ± 7	9 ± 7	9 ± 10	2 (0.062)	2 (0.141)	7 ± 7	15 ± 11	15 ± 10	8 (0.000)*	8 (<0.001)*	5 ± 5	11 ± 9	10 ± 10	6 (<0.001)*	5 (<0.001)*
Transportation	14 ± 9	14 ± 8	12 ± 10	0 (0.788)	-2 (0.322)	13 ± 8	13 ± 13	12 ± 11	0 (0.561)	-1 (0.274)	14 ± 9	15 ± 11	13 ± 9	1 (0.365)	-1 (0.341)
Inactivity	15 ± 11	17 ± 13	18 ± 11	2 (0.490)	3 (0.191)	16 ± 13	15 ± 9	18 ± 12	-1 (0.268)	-2 (0.098)	16 ± 16	17 ± 14	19 ± 16	1 (0.899)	3 (0.007)*

Table 4: Unadjusted comparison of the raw mean ± SD and p-values from regression analysis within the groups, physical activity (PA) pattern and time effects from visit 1 to visit 2 and visit 3, respectively. Visit 1, gestational age of maximum 15 weeks and 0 days; visit 2, the 29th gestational week; visit 3, the 35th gestational week. *Significant difference; SD, Standard deviation; MET, metabolic equivalent of task; h/week, hours/week; CON, standard care; EXE, structured supervised exercise training; MOT, motivational counseling on physical activity.

The total activity did not change from visit 1 to visit 2 in CON, EXE, or MOT, but PA decreased significantly from visit 1 to visit 3 in all three groups (Table 4). PA at moderate intensity was maintained at the same level over the course of pregnancy in CON, EXE, and MOT. However, participants in MOT increased PA at vigorous intensity from visit 1 to visit 2 and visit 3, respectively (Table 4). When combining moderate and vigorous intensity PA (MVPA), the activity level (MET-h/week) did not change through pregnancy in any of the groups (CON: visit 1-2: -1, *P*=.900; visit 1-3: -4, *P*=.356; EXE: visit 1-2: 4, *P*=.102; visit 1-3: 1, *P*=.611; MOT: visit 1-2: 2, *P*=.400, visit 1-3: -5, *P*=.368) (data not shown).

In both EXE and MOT, sports increased significantly from visit 1 to visit 2 and visit 3, respectively, while no changes were observed in CON (Table 4). A comparison between groups revealed that sports was significantly higher in EXE compared to CON and MOT at both visit 2 and visit 3 (Table 3).

Physical activity by doubly labeled water

134 participants (CON: n=24, EXE: n=53, MOT: n=57) completed the DLW test and were included in the analysis. TEE (*P*=.141), AEE (*P*=.383) and PAL (*P*=.658) did not differ between groups (Figure 8).

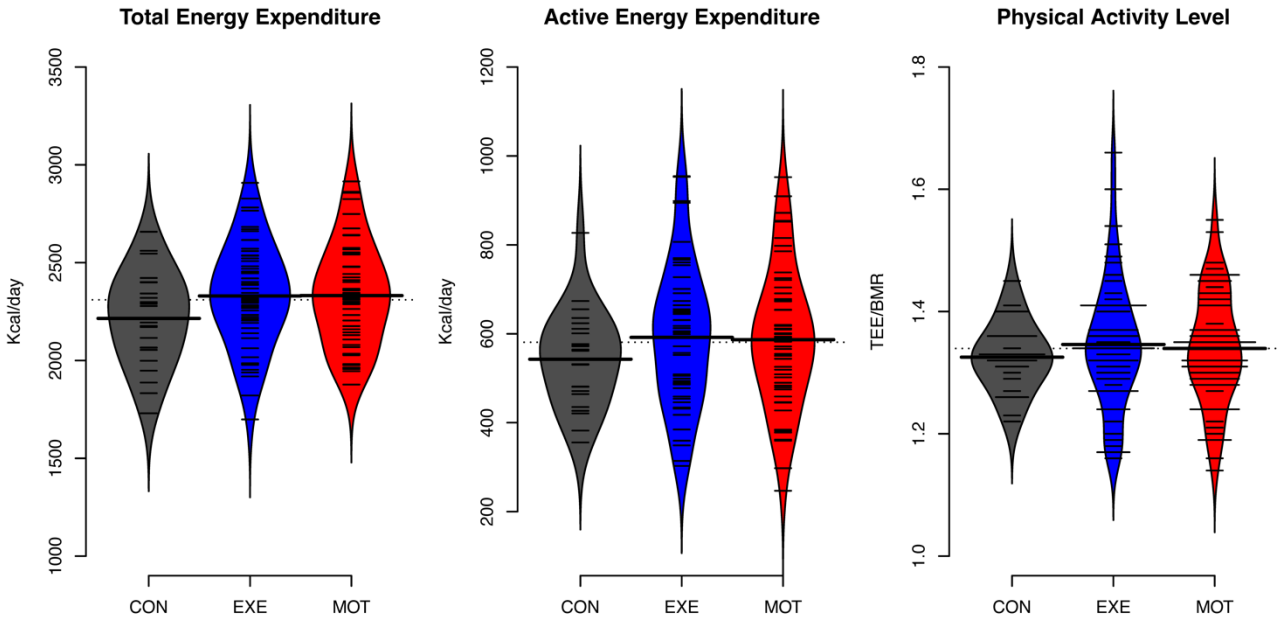

Figure 8: One-way ANOVA test of the doubly labelled water outcomes showed no differences between groups; total energy expenditure (p=0.141), active energy expenditure (p=0.383), physical activity level (p= 0.658). Kcal, kilocalories; TEE, total energy expenditure; BMR; basic metabolic rate, CON, standard care; EXE, structured supervised exercise training; MOT, motivational counselling on physical activity.

Adverse events and serious adverse events

Adverse events (AE) and serious adverse events (SAE) from inclusion to delivery among all participants did not differ between groups (Additional file 1-3).

Discussion

FitMum aimed to investigate the effects of offering EXE or MOT to generate evidence about how to implement PA in healthy pregnant women's life. We hypothesized that both EXE and MOT would increase MVPA in pregnancy compared to CON, but that EXE would be more effective than MOT (33). The study confirmed that EXE was more effective than CON, whereas MOT was not

more effective than CON, and EXE and MOT also did not differ. The number of AE and SAE did not differ between groups.

Effectiveness of physical activity interventions on physical activity level in pregnant women

Few previous RCT's have used strategies like ours to examine how to increase PA in pregnant women and at the same time assessed the PA level by objective methods (13,24,26,42,43). Seneviratne et al. conducted a 16-week stationary biking program in overweight and obese pregnant women and reported improved aerobic fitness compared to controls (24). When determining PA objectively by accelerometry, Hayman et al. found an immediate increase in MVPA after four weeks of tailored PA advice and access to a resource library (26). On the contrary, no increase in PA as determined by accelerometry was found after a combined aerobic and strength exercise program (42), face-to-face individual PA consultations (13) or app-based PA behavior change techniques (43).

Women in EXE were encouraged to participate in three hours of structured supervised exercise training per week, but the participants attended on average less than half of the sessions, and throughout their pregnancy the MVPA level was only 1/3 of the internationally recommended (54 of 150 min/week) (2). As expected, MVPA was positively associated with the number of exercise sessions attended. Noticeably, EXE had a higher level of vigorous intensity PA compared to both CON and MOT. This was supported by a higher maximum heart rate among EXE. Exercising at vigorous intensity is in accordance with recent suggestions for healthy pregnant women (44,45). MOT had a high intervention attendance, but even though MOT contained face-to-face counseling, SMS, activity tracker utilization and behavior change technique as recommended (13,46,47), we found no effect on MVPA compared to CON. The cumulative MVPA in EXE was significantly higher compared to MOT in the late part of pregnancy, and the same tendency was seen between CON and EXE. Interestingly, women who received the online EXE intervention due to COVID-19

restrictions joined 45% more exercise sessions compared to those who received the physical intervention.

Methodologies used to determine physical activity

Combining three different methodologies to assess PA, both objective (activity tracker and DLW) and subjective (PPAQ-DK) methods, gives a comprehensive insight into the complex variable that PA constitutes. The activity tracker offers 24/7 measures of PA and due to its convenience the tracker can be worn for a long period of time. However, commercial trackers are not designed for research purposes and tracker algorithms are unknown. PPAQ is considered one of the most valid and reliable questionnaires for the assessment of PA in pregnant women (27,48), but the inherent bias of self-reported PA is inevitable. The administration of PPAQ-DK may have led to a heightened awareness of activity among participants (48); especially in MOT who received a thorough review of their PA level at the counseling sessions. This might explain the perceived increase in vigorous intensity PA in MOT as determined by PPAQ-DK. DLW is the reference method for the determination of free-living energy expenditure and has previously been used to estimate PA level in pregnant women (36,49), but this is the first intervention study in pregnant women to include DLW. We found no significant differences between groups in TEE, AEE or PAL, but this might be due to a lack of power, as TEE and AEE were 50-100 kcal/day higher in EXE and MOT compared to CON. On the other hand, active kilocalories also did not differ between groups according to tracker data, and total activity (MET-h/week) was similar between groups according to PPAQ-DK. Therefore, the total activity probably did not differ between groups.

Strengths and limitations

FitMum is the first RCT to compare the effectiveness of two different PA interventions in pregnant women. Strengths comprise the robust design based on the power of randomization, which leaves the internal validity high, and the comprehensive assessment of PA. The primary outcome was

measured by a commercial activity tracker, which measured PA continuously, but no data on the validity of the tracker activity measurements has been published. The activity tracker may increase PA due to its motivational impact (47,50), but it might also not capture all activities. Notably, only activities with a MET value of ≥3 in bouts of at least 10 consecutive minutes are reported as MVPA (35), and this might partly explain the relatively low MVPA in the present study. An additional limitation was the impact of COVID-19 and the need to convert the physical interventions into online.

Conclusion

Findings from this RCT demonstrates that offering EXE is more effective than CON to implement MVPA in healthy pregnant women's life. Offering MOT was not more effective than CON, and EXE and MOT also did not differ. The MVPA in the intervention groups did not reach the recommended PA level in pregnancy.

Acknowledgments

The authors would like to acknowledge all women participating in FitMum. Our thanks go to students, research assistants, and staff at Department of Gynaecology and Obstetrics, Nordsjaellands Hospital (NOH), who took part in performing interventions and collecting data. Additionally, we would like to thank the technical staff at the Clinical Research Unit, Department of Clinical Research, NOH; especially Susanne Månsson and Charlotte Pietraszek who engaged themselves in planning practicalities and collecting data.

Conflicts of Interest

The authors declare that they have no conflicts of interest.

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Ethics approval and consent to participate

The study was approved by the Danish National Committee on Health Research Ethics (#H-18011067) and the Danish Data Protection Agency (#P-2019-512). The study adheres to the principles of the Helsinki declaration. Written informed consent was obtained at inclusion.

Authors' contribution

B.S. initiated and directed FitMum. S.dP.K., C.B.R., J.M.B., T.D.C., S.M., S.A.A., E.L and B.S. developed the study protocol. S.dP.K., C.B.R., A.D.A., and I.H. conducted intervention activities and collected data assisted by S.A.A., research assistants and master students. E.L. was the clinical trial manager and supervised the clinical part of FitMum in collaboration with J.M.B., T.D.C., S.M., and B.S. A.K.J. performed and supervised statistical analyses. S.A.A performed the activity tracker data management and J.E.L. contributed with expertise on self-tracking. G.vH. performed the DLW-analysis. S.dP.K. and S.A.A. contributed equally, analyzed data and wrote the manuscript. All authors read, contributed to, and approved the final version of the manuscript.

List of abbreviations

PA: Physical actitivity; MVPA: Moderate-to-vigorous-intensity physical activity; EXE: Structured supervised exercise training; MOT: Motivational counseling on physical activity; CON: Standard care; RCT: Randomized controlled trial; PPAQ: Pregnancy Physical Activity Questionnaire; DLW:

443 Doubly labeled water technique; GA: Gestational age; MET: Metabolic Equivalent of Task (MET);
444 TEE: Total energy expenditure; AEE: Active energy expenditure; BMR: Basal metabolic rate;
445 PAL: Physical activity level; CI: confidence intervals.

446 Additional files

447 Additional file 1: Summary of adverse and serious adverse events.

448 References

449 1. The American College of Obstetricians and Gynecologists. Physical Activity and Exercise
450 During Pregnancy and the Postpartum Period. ACOG Committee Opinion No. 804.
451 Obstetrics and Gynecology. 2020;135:e178-88.

452 2. Bull FC, Al-Ansari SS, Biddle S, Borodulin K, Buman MP, Cardon G, et al. World Health
453 Organization 2020 guidelines on physical activity and sedentary behaviour. Vol. 54, British
454 Journal of Sports Medicine. BMJ Publishing Group; 2020. p. 1451–62.

455 3. Hayes L, McParlin C, Azevedo L, Jones D, Newham J, Olajide J, et al. The Effectiveness of
456 Smoking Cessation, Alcohol Reduction, Diet and Physical Activity Interventions in
457 Improving Maternal and Infant Health Outcomes: A Systematic Review of Meta-Analyses.
458 Nutrients. 2021;13(1036):1–31.

459 4. Sánchez-Polán M, Franco E, Silva-José C, Gil-Ares J, Pérez-Tejero J, Barakat R, et al.
460 Exercise During Pregnancy and Prenatal Depression: A Systematic Review and Meta-
461 Analysis. Frontiers in physiology. 2021;12:1–13.

462 5. Kubler JM, Clifton VL, Moholdt T, Beetham KS. The effects of exercise during pregnancy
463 on placental composition: A systematic review and meta-analysis. Placenta. 2022 Jan
464 1;117:39–46.

6. Kusuyama J, Alves-Wagner AB, Makarewicz NS, Goodyear LJ. Effects of maternal and paternal exercise on offspring metabolism. Nature Metabolism. 2020;2(9):858–72.

7. Bhattacharjee J, Mohammad S, Adamo KB. Does exercise during pregnancy impact organs or structures of the maternal-fetal interface? Tissue and Cell. 2021 Oct 1;72:1–14.

8. Bennett CJ, Walker RE, Blumfield ML, Ma J, Wang F, Wan Y, et al. Attenuation of maternal weight gain impacts infant birthweight: Systematic review and meta-analysis. Journal of Developmental Origins of Health and Disease. 2019;10(4):387–405.

9. Mottola MF, Davenport MH, Ruchat SM, Davies GA, Poitras VJ, Gray CE, et al. 2019 Canadian guideline for physical activity throughout pregnancy. British Journal of Sports Medicine. 2018;52(21):1339–46.

10. Díaz-Burrueco JR, Cano-Ibáñez N, Martín-Peláez S, Khan KS, Amezcua-Prieto C. Effects on the maternal-fetal health outcomes of various physical activity types in healthy pregnant women. A systematic review and meta-analysis. European Journal of Obstetrics & Gynecology and Reproductive Biology. 2021 Jul;262:203–15.

11. Lindqvist M, Persson M, Mogren I. "Longing for individual recognition" – Pregnant women's experiences of midwives' counselling on physical activity during pregnancy. Sexual and Reproductive Healthcare. 2018;15:46–53.

12. Barakat R. An exercise program throughout pregnancy: Barakat model. Birth Defects Research. 2021;113(3):218–26.

13. Currie S, Sinclair M, Murphy MH, Madden E, Dunwoody L, Liddle D. Reducing the Decline in Physical Activity during Pregnancy: A Systematic Review of Behaviour Change Interventions. PLoS ONE. 2013;8(6):1–12.

14. Williams SL, French DP. What are the most effective intervention techniques for changing physical activity self-efficacy and physical activity behaviour - And are they the same? Health Education Research. 2011;26(2):308–22.

15. James P, Morgant R, Merviel P, Saraux A, Giroux-Metges MA, Guillodo Y, et al. How to promote physical activity during pregnancy : A systematic review. Journal of Gynecology Obstetrics and Human Reproduction. 2020;49(9).

16. Wang C, Wei Y, Zhang X, Zhang Y, Xu Q, Sun Y, et al. A randomized clinical trial of exercise during pregnancy to prevent gestational diabetes mellitus and improve pregnancy outcome in overweight and obese pregnant women. American Journal of Obstetrics and Gynecology. 2017;216(4):340–51.

17. Leung Hui A, Back L, Ludwig S, Gardiner P, Sevenhuysen G, Dean HJ, et al. Effects of lifestyle intervention on dietary intake, physical activity level, and gestational weight gain in pregnant women with different pre-pregnancy Body Mass Index in a randomized control trial. BMC Pregnancy and Childbirth. 2014;14(331):1–9.

18. Gaston A, Prapavessis H. Using a combined protection motivation theory and health action process approach intervention to promote exercise during pregnancy. Journal of Behavioral Medicine. 2014;37(2):173–84.

19. Ruart S, Sinnapah S, Hue O, Janky E, Antoine-Jonville S. Prenatal Counseling throughout Pregnancy: Effects on Physical Activity Level, Perceived Barriers, and Perinatal Health Outcomes: A Quasi-Experimental Study. International Journal of Environmental Research and Public Health. 2020;17(23):8887.

20. Hawkins M, Chasan-Taber L, Marcus B, Stanek E, Braun B, Ciccolo J, et al. Impact of an

exercise intervention on physical activity during pregnancy: The behaviors affecting baby and you study. American Journal of Public Health. 2014;104(10):e74–81.

21. Renault KM, Nørgaard K, Nilas L, Carlsen EM, Cortes D, Pryds O, et al. The Treatment of Obese Pregnant Women (TOP) study: A randomized controlled trial of the effect of physical activity intervention assessed by pedometer with or without dietary intervention in obese pregnant women. American Journal of Obstetrics and Gynecology. 2014;210:134.e1-9.

22. Barakat R, Perales M, Cordero Y, Bacchi M, Mottola MF. Influence of Land or Water Exercise in Pregnancy on Outcomes: A Cross-sectional Study. Medicine and Science in Sports and Exercise. 2017;49(7):1397–403.

23. Poston L, Bell R, Croker H, Flynn AC, Godfrey KM, Goff L, et al. Effect of a behavioural intervention in obese pregnant women (the UPBEAT study): a multicentre, randomised controlled trial. The Lancet Diabetes & Endocrinology. 2015;3(10):767–77.

24. Seneviratne S, Jiang Y, Derraik J, Mccowan L, Parry G, Biggs J, et al. Effects of antenatal exercise in overweight and obese pregnant women on maternal and perinatal outcomes: a randomised controlled trial. BJOG. 2016;123:588–97.

25. Pearce E, Evenson K. Strategies to promote physical activity during pregnancy. American journal of lifestyle medicine. 2013;7(1):1–19.

26. Hayman M, Reaburn P, Browne M, Vandelanotte C, Alley S, Short CE. Feasibility , acceptability and efficacy of a web-based computer-tailored physical activity intervention for pregnant women - the Fit4Two randomised controlled trial. 2017;1–10.

27. Chasan-Taber L, Schmidt MD, Roberts DE, Hosmer D, Markenson G, Freedson PS. Development and validation of a pregnancy physical activity questionnaire. Medicine and

Science in Sports and Exercise. 2004;36(10):1750–60.

28. Krøner FH, Knudsen S de P, Roland CB, Alomairah SA, Molsted S. Validity and reliability of the Danish version of the pregnancy physical activity questionnaire to assess levels of physical activity during pregnancy. Journal of Maternal-Fetal and Neonatal Medicine. 2020;

29. Wong WW, Roberts SB, Racette SB, Das SK, Redman LM, Rochon J, et al. The Doubly Labeled Water Method Produces Highly Reproducible Longitudinal Results in Nutrition Studies. Journal of Nutrition. 2014;144:777–83.

30. Santini C, Dos T, Imakawa S, Dantas Moisés EC. Physical Activity during Pregnancy: Recommendations and Assessment Tools. Rev Bras Ginecol Obstet. 2017;39:424–32.

31. Abeysekera M V, Morris JA, O 'sullivan AJ. Techniques to measure free-living energy expenditure during pregnancy – A guide for clinicians and researchers. Obstetric Medicine. 2014;7(2):60–5.

32. Roland CB, Knudsen S de P, Alomairah SA, Andersen AD, Bendix J, Clausen TD, et al. Structured supervised exercise training or motivational counselling during pregnancy on physical activity level and health of mother and offspring: FitMum study protocol. BMJ Open. 2021;11(3):1–11.

33. Statistical Analysis Plan (SAP) for the FitMum randomized controlled trial [Internet]. Statistical Analysis Plan (SAP) for the FitMum randomized controlled trial. 2020. Available from: https://clinicaltrials.gov/ProvidedDocs/30/NCT03679130/SAP_000.pdf

34. The Danish Health Authorities. Recommendations for pregnant women [Internet]. 2021. Available from: https://www.sst.dk/da/viden/fysisk-aktivitet/anbefalinger-om-fysisk-aktivitet/gravide

35. Garmin [Internet]. Available from: https://www.garmin.com

36. Speakman JR, Yamada Y, Sagayama H, Berman ESF, Ainslie PN, Andersen LF, et al. A standard calculation methodology for human doubly labeled water studies. Cell Reports Medicine. 2021 Feb 16;2(2):100203.

37. Hronek M, Zadak Z, Hrnciarikova D, Hyspler R, Ticha A. New equation for the prediction of resting energy expenditure during pregnancy. Nutrition (Burbank, Los Angeles County, Calif). 2009;25(9):947–53.

38. R Core Team (2020). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. [Internet]. Available from: https://www.r-project.org/

39. van Buuren S, Groothuis-Oudshoorn K. mice: Multivariate imputation by chained equations in R. Journal of Statistical Software. 2011 Dec;45(3):1–67.

40. Wood SN. Generalized additive models: An introduction with R, second edition. Generalized Additive Models: An Introduction with R, Second Edition. 2017;1–476.

41. Koenker R, Ng P. Inequality constrained quantile regression. Sankhya: The Indian Journal of Statistics. 2005;67(2):418–40.

42. Oostdam N, Van Poppel MNM, Wouters MGAJ, Eekhoff EMW, Bekedam DJ, Kuchenbecker WKH, et al. No effect of the FitFor2 exercise programme on blood glucose, insulin sensitivity, and birthweight in pregnant women who were overweight and at risk for gestational diabetes: Results of a randomised controlled trial. BJOG: An International Journal of Obstetrics and Gynaecology. 2012;119(9):1098–107.

43. Sandborg J, Söderström E, Henriksson P, Bendtsen M, Henström M, Leppänen MH, et al. Effectiveness of a Smartphone App to Promote Healthy Weight Gain, Diet, and Physical Activity During Pregnancy (HealthyMoms): Randomized Controlled Trial. JMIR mHealth and uHealth. 2021;9(3).

44. Meah VL, Davies GA, Davenport MH. Why can't i exercise during pregnancy? Time to revisit medical "absolute" and "relative" contraindications: Systematic review of evidence of harm and a call to action. British Journal of Sports Medicine. 2020;54(23):1395–404.

45. Australian Government. Department of Health. Physical activity and exercise guidelines for pregnancy [Internet]. 2021. Available from: https://www.health.gov.au/health-topics/physical-activity-and-exercise/pregnancy

46. Leonard KS, Evans MB, Oravecz Z, Smyth JM, Symons Downs D. Effect of Technology-Supported Interventions on Prenatal Gestational Weight Gain, Physical Activity, and Healthy Eating Behaviors: a Systematic Review and Meta-analysis. Journal of Technology in Behavioral Science. 2021;6(1):25–41.

47. Brickwood KJ, Watson G, O'brien J, Williams AD. Consumer-based wearable activity trackers increase physical activity participation: Systematic review and meta-analysis. Vol. 7, JMIR mHealth and uHealth. 2019.

48. Sattler MC, Jaunig J, Watson ED, van Poppel MNM, Mokkink LB, Terwee CB, et al. Physical Activity Questionnaires for Pregnancy: A Systematic Review of Measurement Properties. Vol. 48, Sports Medicine. Springer International Publishing; 2018. p. 2317–46.

49. Löf M. Physical activity pattern and activity energy expenditure in healthy pregnant and non-pregnant Swedish women. European Journal of Clinical Nutrition. 2011;65129(10):1295–

301.

50. Laranjo L, DIng Di, Heleno B, Kocaballi B, Quiroz JC, Tong HL, et al. Do smartphone applications and activity trackers increase physical activity in adults? Systematic review, meta-analysis and metaregression. Vol. 55, British Journal of Sports Medicine. Br J Sports Med; 2021. p. 422–32.

		ALL	CON	EXE	MOT
		n=220	n=45	n=87	n=87
Any adverse or serious adverse event		148 (67)	28 (62)	61 (70)	59 (68)
Serious adverse event		17 (8)	3 (7)	6 (7)	8 (9)
Adverse or serious adverse event that led to discontinuation in EXE or MOT		4 (2)	0 (0)	3 (3)	1 (1)
Adverse or serious adverse event that led to withdrawal from the trial		6 (3)	1 (2)	4 (5)	1 (1)
Adverse events that occurred in ≥10% of all participants					
	Foetal hypokinesia	47 (21)	7 (16)	23 (26)	17 (20)
	Low back and pelvic girdle pain	41 (19)	4 (9)	19 (22)	18 (21)

Additional file 1: Summary of adverse and serious adverse events from inclusion to delivery among all participants presented with preferred terms in Medical Dictionary for Regulatory Activities, version 24.0. One participant dropped out before randomization and therefore the number of participants in CON, EXE and MOT equals 219. Data are presented as number of participants (%). CON, standard care; EXE, structured supervised exercise training; MOT, motivational counseling on physical activity.

		ALL	CON	EXE	MOT
		n=220	n=45	n=87	n=87
All					
	≥ 1 adverse event	141 (64)	28 (62)	58 (67)	55 (63)
Pregnancy, puerperium and perinatal conditions		118 (54)	22 (49)	49 (56)	47 (54)
	Foetal hypokinesia	47 (21)	7 (16)	23 (26)	17 (20)
	Low back and pelvic girdle pain	41 (19)	4 (9)	19 (22)	18 (21)
	Uterine contractions during pregnancy	20 (9)	1 (2)	10 (12)	9 (10)
	GDM	13 (6)	2 (4)	5 (6)	6 (7)
	Small for dates baby (<-1.28 SD)	11 (5)	3 (7)	1 (1)	7 (8)
	Large for dates baby (>1.28 SD)	13 (6)	1 (2)	7 (8)	5 (6)
	Preeclampsia/gestational hypertension/HELLP/eclampsia (GA≥34 weeks)	11 (5)	2 (4)	5 (6)	4 (5)
	Premature delivery (GA 34+0 - 36+6 weeks)	3 (1)	2 (4)	1 (1)	0 (0)
	Cholestasis of pregnancy	3 (1)	0 (0)	0 (0)	3 (3)
	Foetal malformation	3 (1)	2 (4)	1 (1)	0 (0)
	Hyperemesis gravidarum	2 (0.9)	1 (2)	0 (0)	1 (1)
	Threathened preterm labor	1 (0.5)	0 (0)	0 (0)	1 (1)
	Gestational oedema	1 (0.5)	0 (0)	0 (0)	1 (1)
Reproductive system and breast disorders		17 (8)	4 (9)	6 (7)	7 (8)
	Vaginal haemorrhage	17 (8)	4 (9)	6 (7)	7 (8)
	Ovarian rupture	1 (0.5)	0 (0)	1 (1)	0 (0)
Infections and infestations		21 (10)	7 (16)	6 (7)	8 (9)
	Urinary tract infection	10 (5)	3 (7)	3 (3)	4 (5)
	Beta haemolytic streptococcal infection	6 (3)	3 (7)	2 (2)	1 (1)
	Other	6 (3)	1 (2)	2 (2)	3 (3)
Accidents and Injuries		7 (3)	2 (4)	3 (3)	2 (2)
	Unrelated to intervention	6 (3)	2 (4)	2 (2)	2 (2)
	Related to intervention*	1 (0.5)	0 (0)	1 (1)	0 (0)
Skin and subcutaneous tissue disorders		12 (6)	2 (4)	3 (3)	7 (8)
	Rash	9 (4)	2 (4)	3 (3)	4 (5)
	Prurigo	3 (1)	0 (0)	0 (0)	3 (3)
Nervous system disorders		10 (5)	1 (2)	5 (6)	4 (5)
	Migraine	5 (2)	0 (0)	1 (1)	4 (5)
	Headache	2 (0.9)	1 (2)	1 (1)	0 (0)
	Dizziness	2 (0.9)	0 (0)	1 (1)	1 (1)
	Carpal tunnel syndrome	2 (0.9)	0 (0)	2 (2)	0 (0)
Psychiatric disorders		4 (2)	1 (2)	0 (0)	3 (3)
Gastrointestinal disorders		3 (1)	0 (0)	2 (2)	1 (1)
	Constipation	2 (0.9)	0 (0)	2 (2)	0 (0)
	Abdominal pain upper	1 (0.5)	0 (0)	0 (0)	1 (1)
Other		9 (4)	3 (7)	3 (3)	3 (3)

Additional file 2: All adverse events (AE) from inclusion to delivery presented with preferred terms according to the Medical Dictionary for Regulatory Activities, version 24.0. Values are number of participants (%) with ≥ 1 AE. AEs include all self-reported AEs by participants at test visits and other AEs that the research group became aware of during

the study period. One participant dropped out before randomization and therefore the number of participants in CON, EXE and MOT equals 219. *Injury related to intervention included abdominal pain without verified reason after one exercise training session. CON, standard care; EXE, structured supervised exercise training; MOT, motivational counseling on physical activity.

		ALL	CON	EXE	MOT
		n=220	n=45	n=87	n=87
All					
	No. of participants who experienced ≥ 1 serious adverse event	17 (8)	3 (7)	6 (7)	8 (9)
	No. of serious adverse events	20	3	6	11
Pregnancy, puerperium and perinatal conditions		16 (7)	3 (7)	6 (7)	7 (8)
	Large for gestational age (>2 SD)	5 (2)	1 (2)	0 (0)	4 (5)
	Small for gestational age (<-2 SD)	4 (2)	1 (2)	2 (2)	1 (1)
	Missed abortion	3 (1)	0 (0)	2 (2)	1 (1)
	Premature delivery (GA<34 weeks)	3 (1)	1 (2)	0 (0)	2 (2)
	Shoulder dystocia	2 (0.9)	0 (0)	1 (1)	1 (1)
	Pelvic haematoma obstetric	1 (0.5)	0 (0)	1 (1)	0 (0)
	Preeclampsia/gestational hypertension/HELLP/eclampsia (GA<34 weeks)	1 (0.5)	0 (0)	0 (0)	1 (1)
Accidents and injuries					
	Car accident*	1 (0.5)	0 (0)	0 (0)	1 (1)

Additional file 3: All serious adverse events (SAE) from inclusion to delivery are presented with preferred terms according to the Medical Dictionary for Regulatory Activities, version 24.0. Values are the number of participants (%) with ≥ 1 SAE. SAEs include all self-reported SAEs by participants at test visits and other SAEs that the research group became aware of during the study period. One participant dropped out before randomization and therefore the number of participants in CON, EXE and MOT only equals 219. *Resulted in a broken leg. CON, standard care; EXE, structured supervised exercise training; MOT, motivational counseling on physical activity.

Paper 3

Physical activity during pregnancy: a mixed methods process evaluation of the FitMum randomised controlled trial interventions

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Abstract

Background: Physical activity (PA) at moderate intensity is recommended to healthy pregnant women. The three-arm FitMum randomised controlled trial showed that it was possible to increase PA during pregnancy with structured supervised exercise training (EXE). The other intervention with motivational counselling on PA (MOT) did not increase PA compared to standard care. However, given the complexity of PA interventions it is not sufficient to limit evaluation activities to test effectiveness to fully understand their impact. This process evaluation aimed to achieve a greater understanding of the implementation and mechanisms of impact of EXE and MOT.

Methods: A mixed methods process evaluation was conducted using the Medical Research Council's process evaluation framework by assessing implementation (reach, fidelity and dose) and mechanisms of impact of the two interventions provided to pregnant women in the FitMum study. Data was collected quantitatively (n=220) and qualitatively (n=20) continuously during the FitMum study.

Results: The interventions *reached* educated pregnant women with high autonomy of working and everyday life. Most participants (78%) were recruited at their first-trimester ultrasonic scan. The reasons to participate were personal (91%) and altruistic (56%). The intervention *dose* was *delivered* as intended with high *fidelity*. A low *dose received* in EXE was partly explained by the interventions favouring participants with a flexible everyday life and a supportive social network. *Dose received* in EXE was increased during COVID-19. The scheduled EXE sessions represented an intervention connection whereas MOT participants found themselves PA self-determined. *Mechanisms of impact* comprised of commitment and perception of empowerment and PA.

Conclusion: The FitMum study reached a selected group of pregnant women. The PA interventions were well delivered with high fidelity. Despite high intervention accessibility, the low dose

received in EXE may be due to a need for time for other commitments in everyday life. Mechanisms of impact comprised of intervention commitment, flexibility and empowerment towards PA. PA was considered as constrained activities in EXE and a part of daily activities in MOT. During COVID-19, the dose received in EXE increased compared to the previous physical setup, and future interventions should consider a combination of physical and online exercise training.

Trial registration: The study was approved by the Danish National Committee on Health Research Ethics (#H-18011067) and the Danish Data Protection Agency (#P-2019-512). The study adheres to the principles of the Helsinki declaration. Written informed consent was obtained at inclusion.

Keywords: Complex interventions, process evaluation, mixed methods, intervention research, physical activity, pregnancy

Background

Physical activity (PA) during pregnancy is a safe and effective way of reducing pregnancy related complications including excessive gestational weight gain (1,2), gestational diabetes mellitus (3,4), gestational hypertension, pre-eclampsia (5,6), preterm delivery and caesarean section (4,7–9), and depression (10). Harrison et al. showed in a systematic review that most pregnant women believe that PA during pregnancy is important and beneficial (11). Despite this, a large percentage of pregnant women do not achieve sufficient PA levels during pregnancy, as advised by the official recommendations, and some pregnant women even decrease their PA level over the course of pregnancy (5). Intrapersonal barriers including fatigue, lack of time and motivation, and pregnancy

discomforts, are the most frequently reported factors related to low PA levels (11,12). In addition, some pregnant women feel uncertain about whether participation in exercise interventions might harm their unborn child (13).

Various intervention strategies have been tested to promote PA during pregnancy. However, few studies have reported any superior interventions for increasing PA (14,15). In addition, intervention adherence has varied, often with no or inconclusive explanations (16,17). Given the complexity of PA interventions and the need to evaluate their impact, it is not sufficient to limit evaluation activities to test effectiveness.

Our research group developed the FitMum study to investigate the effect of standard care (CON), structured supervised exercise training (EXE) or motivational counselling on PA (MOT) in healthy, inactive pregnant women (18). The effect evaluation of the FitMum study (Knudsen et al., under review) showed that participants in EXE had a higher level of moderate-to-vigorous-intensity PA (MVPA) (min/week) compared to participants in CON. However, the mean MVPA level in EXE corresponded to one third of the internationally recommended level. No effect on MVPA was found in MOT compared to CON, and MVPA did not differ significantly between MOT and EXE. To fully understand the interventions process evaluation is needed to monitor and document the implementation of interventions to avoid simplification of essential details (19,20). In this way, it is possible to better understand why an intervention was or was not successful and to uncover any impact mechanisms behind the results achieved (19,20). However, despite its importance, only few studies have provided knowledge regarding the mechanisms behind prenatal PA interventions (21–23).

Indeed, the UK Medical Research Council guideline for process evaluation from 2015 (19) suggests that both quantitative and qualitative methods are equally essential in process evaluations to

examine if the intervention reached the audience as intended (*reach*), if components of the complex intervention were provided as intended (*fidelity*), the quantity and quality of what was actually implemented (*dose*) and how the interventions produced or prevented changes (*mechanisms of impact*).

This mixed methods process evaluation aimed to improve the understanding of the effects on PA that emerged from the effect evaluation of the FitMum study and to gain insight into factors influencing the interventions by assessing the implementation (reach, fidelity and dose) and mechanisms of impact of the two complex PA interventions delivered to pregnant women participating in the FitMum study.

Methods

Study design

The process evaluation of the FitMum study adapted the Medical Research Council process evaluation framework developed by Moore et al. in 2015 (19). The framework was applied to investigate implementation components of the two interventions delivered in the FitMum study covering intervention reach, fidelity, dose and mechanisms of impact. The process evaluation was nested inside the FitMum study with a mixed methods intervention design applied to let the qualitative strands help interpret and contextualise the quantitative results (24).

The FitMum study was a single-site, three-arm randomised controlled trial that included 220 healthy inactive (less than one hour/week of MVPA during early pregnancy) pregnant women in a two-year period from October 2018 to October 2020. One participant was lost to follow-up before randomisation; hence 219 participants were randomised into CON (n=45), EXE (n=87), or MOT (n=87). CON received standard care. The interventions (EXE and MOT) ran from randomisation to

delivery targeting a minimum 30 min/day of moderate intensity PA. The content of the two interventions are illustrated in Figure 1 and described in detail elsewhere (18).

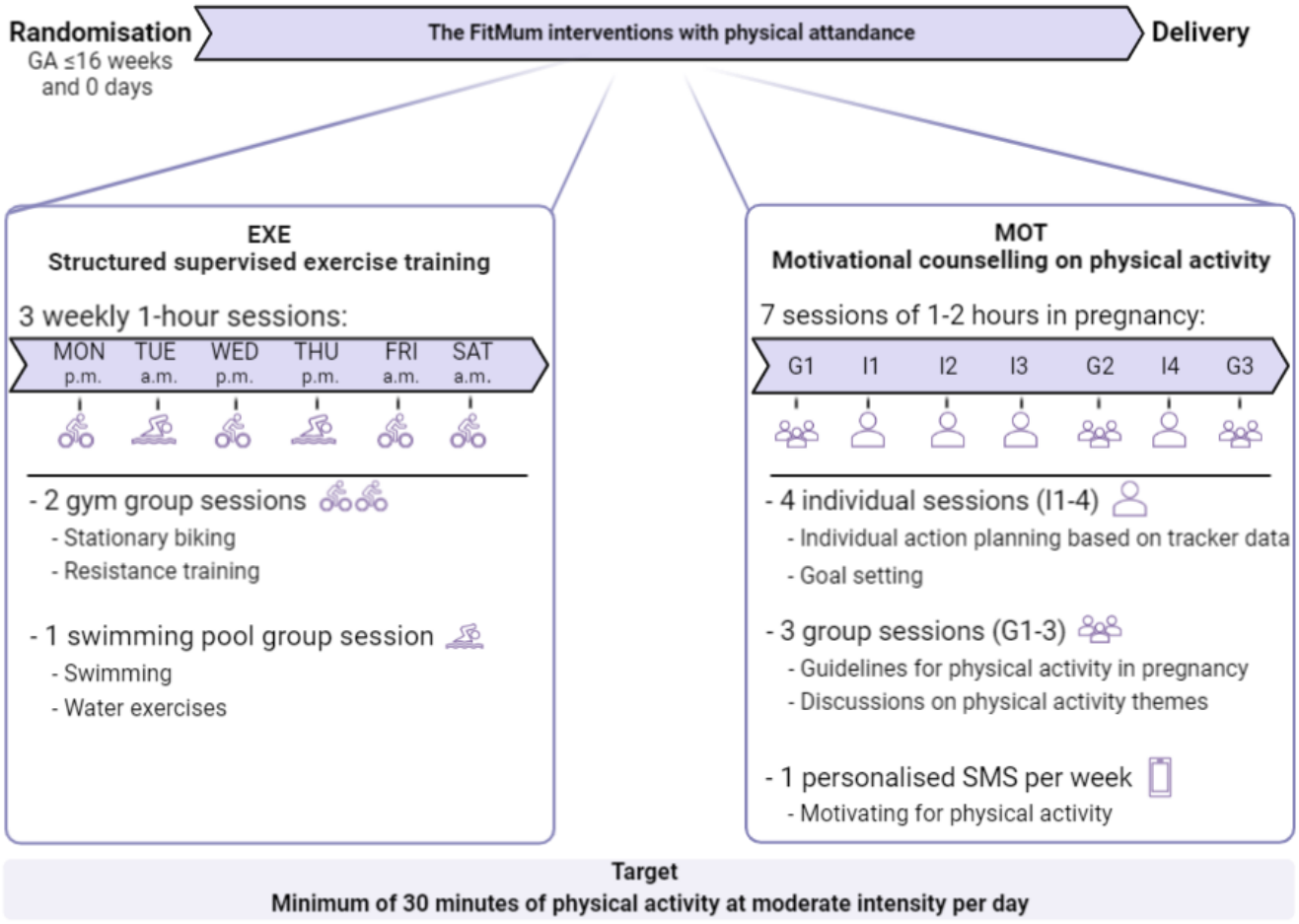

Figure 1. Content of the structured supervised exercise intervention (EXE) and the motivational counselling on physical activity (MOT) as they were designed originally. EXE sessions were offered six days/week and the participants in EXE were recommended to choose three sessions/week. During the six days/week, gym sessions were offered four days (Mon, Wed, Fri and Sat). Swimming pool sessions were offered twice/week (Tue and Thu). Morning sessions were held three times/week (Tue 7:15 am, Fri 7:00 am and Sat 9:00 am); Afternoon sessions were held three times/week (Mon 4:30 pm, Wed 4:30 pm and Thu 4:45 pm). Participants in MOT were offered seven sessions during the intervention period. Distribution of the seven counselling sessions in MOT: G1, <3 weeks after randomisation; I1, 4-6 weeks after randomisation; I2 and I3 equally distributed between I1 and G2; G2, gestational age (GA) 24-26 weeks;

I4, GA 31-32 weeks, G3, GA 35-37 weeks. Mon, Monday; Tue, Tuesday; Wed, Wednesday; Thu, Thursday; Fri, Friday; Sat, Saturday. G, group counselling session; I, individual counselling session. The figure is created with Biorender.com.

Data collection and components

Data collection methods included quantitative data and semi-structured individual interviews of participants. Table 1 presents the process evaluation dimensions, their definitions and corresponding measurements.

Process evaluation dimension	Definition	Quantitative measures	Qualitative inquiries
Reach	The proportion of women included in the FitMum study	Number of women included in the FitMum study and their reasons to participate	What were the reasons to participate?
Fidelity	To what extent the interventions were implemented as intended according to the protocol	How COVID-19 restrictions affected intervention implementation	Not obtained
		How COVID-19 affected intervention participation	
Dose delivered	The number of intended intervention sessions conducted	How often the sessions were offered	How was intervention accessibility experienced?
			How did participants organise themselves in their everyday life to participate in the interventions?
Dose received	To what extent participants used resources as recommended	To what extent participants adhered to the interventions	What barriers and facilitators did the participants meet towards physical activity?
Mechanisms of impact	How the delivered interventions produced changes	Not obtained	How did the participants experience and perceive the impact of the interventions and what were their physical activity motives?

Table 1. Data collection of the process evaluation of structured supervised exercise training (EXE) and motivational counselling on physical activity (MOT). The dimensions addressed are in relation to implementation (reach, fidelity, and dose) and mechanisms of impact. Quantitative measures of reach were obtained at enrolment from all 220 included participants. Quantitative measures of fidelity, dose delivered and received, and mechanisms of impact were obtained during the intervention period from 87 participants randomised to each interventions group. All qualitative inquiries were obtained from 10 participants in EXE and 10 participants in MOT at the 35th gestational week.

Quantitative measures

Reach was covered at inclusion by asking participants where they were introduced to the FitMum study and their immediate reason(s) to participate. Answers were quantified into predefined options based on the recruitment strategy (online booking of ultrasonic scan, outpatient clinic at the hospital, posters at e.g. the general practitioner, social media, family and friends, online pregnancy related platforms or other options) and generally known reasons for participating in intervention studies (to increase PA, contribute to research, closer contact with health professionals, interact with peers or other reasons). *Fidelity* was assessed during the study period comparing the FitMum study protocol (18) with how intervention components were carried out, e.g. before and during COVID-19. *Dose* was assessed administratively by recording intervention attendance after each session from randomisation to delivery.

Qualitative interviews

Semi-structured individual interviews (25) were conducted between July and December 2019 (before the COVID-19 restrictions) on a subset of enrolled participants during a test visit at the 35th gestational week. One woman cancelled the visit and five women were prevented from participating in an interview for different reasons. An interview guide (25) with the following themes was used: Inclusion and participation in the FitMum study, perception of the content in the interventions, PA

in everyday life, barriers and enablers towards PA and the importance of PA during pregnancy (Supplementary material: interview guide). *Reach* was assessed by participants elaborating on their reasons for participating. *Dose* was evaluated by participants giving insight to their everyday lives and the way they interacted with the interventions. *Mechanisms of impact* was covered by the participants' experience of the impact of the intervention components and key enablers and barriers that may influence the implementation and effectiveness of the interventions.

All interviews were conducted by project staff at the FitMum study facilities at Nordsjaellands Hospital and lasted from 31 min to 1 hour and 3 min, with an average of 48 min. All interviews were audio-recorded, added to the Research Electronic Data Capture (REDCap) and subsequently transcribed verbatim in their full length.

Analysis

Integration of quantitative and qualitative data

Data analyses of quantitative and qualitative data were performed independently, and the findings were embedded within the mixed methods intervention design applied to let the qualitative strands help interpret and contextualise of the quantitative results (24). Quantitative and qualitative data were equally prioritised and presented theme-by-theme using a "weaving technique" reported in a narrative form (26). Linkages between the quantitative and the qualitative findings led to three anticipated outcomes: 1) confirmation, when results from quantitative and qualitative material confirmed results of each other, 2) expansion, when results of analyses of quantitative and qualitative data were different and extended insights occurred and 3) discrepancy, when results of analyses of quantitative and qualitative data were inconsistent and contradicted each other (26,27).

Quantitative data to explore reach, fidelity and dose

Descriptive statistics of characteristics of the participants in the FitMum study are presented as means ± standard deviation for symmetric distributions and medians (interquartile ranges) for skewed data. Categorical variables are presented as number (n) and frequency (%). Wald-based 95% confidence interval are given for reported intervention attendance estimates. Analysis regarding study alterations due to the COVID-19 restrictions included participants who received either exclusively the physical.

Qualitative analysis to explore reach, dose, and mechanisms of impact

A thematic content analysis of the interviews was performed using NVivo version 1.6.1 (28,29). First, SdPK (first author) obtained the total impression of the material by listening to all audio-recordings and reading all transcripts. Second, the interviews were coded separately on a line-by-line basis and initially organized according to the topic of questions from the interview guide in a systematic text condensation (29). Codes were then inductively derived considering different intervention components and the dimensions of the evaluation framework. SdPK and JBø (co-author) discussed the coding structure, and issues were resolved by consensus. Third, SdPK and JBø developed themes to map each dimension of the framework. Identified themes were supported by direct quotes from the interviewees. The interview guide and all quotes involved in the manuscript were translated from Danish to English.

Results

Characteristics of participants

Two hundred and twenty healthy, inactive pregnant women were included in the FitMum study and 219 with a median gestational age of 12.9 (9.4-13.9) weeks were randomised (Table 2).

	Participants randomised to the FitMum study				Interviewees		
	ALL	CON	EXE	MOT	All	EXE	MOT
	n=219	n=45	n=87	n=87	n=20	n=10	n=10
Age (years), mean (SD)	31.5 (4.3)	32.0 (4.6)	31.1 (4.3)	31.7 (4.1)	32.3 (4.0)	31.2 (3.4)	33.3 (4.5)
Gestational age at inclusion (weeks), median (IQR)	12.9 (9.4-13.9)	12.9 (9.7-13.9)	12.6 (9.3-13.7)	12.9 (9.6-13.9)	11.3 (9.7-13.1)	11.5 (9.7-13.5)	11.2 (9.9-12.8)
Weight at inclusion (kg), mean (SD)	75.4 (15.3)	72.0 (13.7)	76.2 (17.4)	76.3 (13.8)	73.3 (17.1)	72.7 (15.6)	73.9 (19.4)
Prepregnancy BMI (kg/m^2)*, median (IQR)	24.1 (21.8-28.7)	23.5 (21.3-26.8)	25.2 (21.6-29.8)	24.1 (22.4-28.9)	23.7 (21.5-28.1)	23.7 (21.8-27.3)	24.3 (21.3-30.3)
Nulliparity, n (%)	82 (37)	16 (36)	40 (46)	26 (30)	8 (40)	4 (40)	4 (40)
Educational level							
School ≥12 years, n (%)	191 (87)	41 (91)	74 (85)	76 (87)	18 (90)	9 (90)	9 (90)
Further education ≥3 years, n (%)	175 (80)	33 (73)	73 (84)	69 (79)	18 (90)	9 (90)	9 (90)
Employed or studying, n (%)	199 (91)	39 (87)	83 (95)	77 (89)	17 (85)	9 (90)	8 (80)

Table 2. Baseline characteristics of the participants in FitMum and the subset of participants who were interviewed. Descriptive data are presented as means ± SD for symmetrically distributions, medians (IQR) for skewed data, and n (%). *Prepregnancy body mass index (BMI) is calculated based on n=218 (CON: n=45, EXE: n=86, MOT: n=87) due to a missing value. School ≥12 years corresponds to high school. Further education ≥3 years corresponds to a university degree (bachelor or master level). No statistical comparisons have been performed on descriptive characteristics in accordance with CONSORT recommendations. SD, standard deviation; IQR, interquartile range; n, number; CON, control group; EXE, structured supervised exercise training; MOT, motivational counselling on physical activity.

A total of 20 interviews were conducted; ten interviews of participants randomised to EXE or MOT, respectively. Maternal baseline characteristics of the subset of 20 interviewees and the 219 randomised participants in the FitMum study did not seem to differ. Compared with the general population of pregnant women who delivered at Nordsjaellands Hospital in 2017, participants in the FitMum study were more likely to have an educational level at or above a bachelor's degree (80% vs. 29%).

Reach

Of the included participants, 58% (n=128) reported, that they were introduced to the FitMum study while booking their first-trimester ultrasonic scan, 20% (n=45) at the outpatient clinic at Nordsjaellands Hospital, 15% (n=32) via posters at e.g. their general practitioner, 10% (n=23) via social media, 8% (n=18) via friends or family, 5% (n=12) via an online Danish pregnancy platform

(30), and 9% (n=19) via other options. Before randomisation, 91% (n=201) stated that they wanted to participate in the study to increase their level of PA, 56% (n=123) to take part in and contribute to research, 7% (n=16) to have a closer contact with health professionals, 5% (n=10) to interact with other pregnant women, and 8% (n=18) had other reasons. Participants in both intervention groups expressed in the interviews that the desire to become more physically active was mostly for the woman's own good and arose from various factors; in general, there was an underlying understanding that the body naturally weakens during pregnancy. Hence, a physically active pregnancy was equated to an uncomplicated pregnancy with e.g. less pain and decreased risk of pregnancy complications. In extension, the participants reasoned that an uncomplicated pregnancy would lead to an uncomplicated delivery and emphasised that being in a good physical condition was a prerequisite for an uncomplicated delivery. The women assumed that their PA level would be low and mainly reserved to general everyday activities if not being a part of the interventions. One woman linked a hypothetically low PA level with self-blame and expressed that:

"(If not being a part of the intervention) I could fear that I was still on the couch at home. That I hadn't gotten my act together. And then I think I would have felt guilty if I then had an awful delivery. I could blame myself a bit for that, actually" (Participant no. 117, EXE).

It appeared that the desire to become more physically active unconsciously resulted in a feeling of responsibility not only for the woman herself, but also in terms of the delivery outcome and the well-being of the child. In addition, excessive gestational weight gain was framed as a concern. Some women stated that they had gained more weight than wanted in their previous pregnancies and by being physically active they wanted to limit their weight gain in their present pregnancy. One woman explained that she, because of being overweight, felt a greater responsibility to be physically active during the pregnancy. She expressed a concern about being judged by others if she did not make an effort to improve the health of her unborn child through PA.

Fidelity

The original planned sessions were held for 17.5 months with 120 participants (CON: n=24, EXE: n=48, MOT: n=48) receiving the physical interventions only. On March 11th, 2020 COVID-19 restrictions were implemented in Denmark. Thus, the original setup of the interventions with physical attendance was altered into an online design of both interventions with participants attending from home (18). In the altered interventions, EXE sessions were held virtually (except for three months with swimming pool access) with 30 min of individual, offline and self-selected aerobic PA followed by 30 min online structured aerobic and strength PA in groups. In MOT, the content and distribution of group and individual sessions remained the same, however held online (Figure 2).

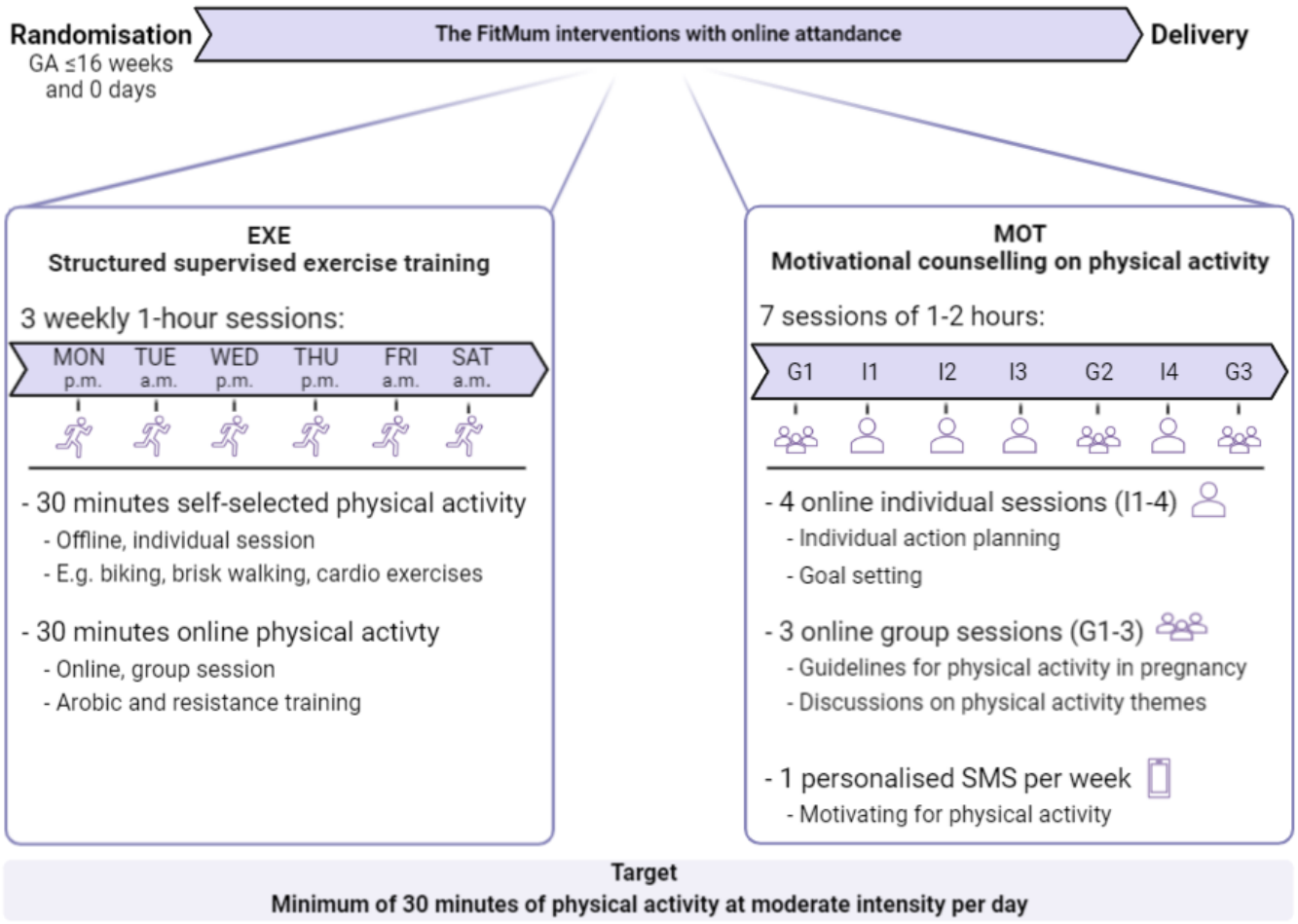

Figure 2. Content of EXE and MOT designed to be delivered online. The period covers participation from March 12th, 2020 to May 2021 due to COVID-19 restrictions. EXE sessions were offered six days/week and participants in EXE were recommended to choose three sessions/week. The sessions were home-based and held online. Morning sessions were held three times/week (Tue 7:15 am, Fri 7:00 am and Sat 9:00 am); Afternoon sessions were held three times/week (Mon 4:30 pm, Wed 4:30 pm and Thu 4:45 pm). Participants in MOT were offered seven home-based, online sessions during the intervention period. Distribution of the seven counselling sessions in MOT: G1, <3 weeks after randomisation; I1, 4-6 weeks after randomisation; I2 and I3 equally distributed between I1 and G2; G2, gestational age (GA) 24-26 weeks; I4, GA 31-32 weeks, G3, GA 35-37 weeks. Mon, Monday; Tue, Tuesday; Wed, Wednesday; Thu, Thursday; Fri, Friday; Sat, Saturday. G, group counselling session; I, individual counselling session; EXE, structured supervised exercise training; MOT, motivational counselling on physical activity. The figure is created with Biorender.com.

The online sessions ran for 14.5 months with 63 participants (CON: n=14, EXE: n=25, MOT: n=24) receiving the online interventions only as they were included and delivered during the pandemic. Thirty-six participants (CON: n=7, EXE: n=14, MOT: n=15) received both the physical and online intervention as they were included before the COVID-19 restrictions but gave birth during the pandemic. There were no differences in the lost to follow-up rate between participants who were included before or during COVID-19 restrictions.

Dose delivered

EXE sessions were delivered six days a week and the participants were recommended to choose three of the sessions (Figure 1). During the study period of approximately 32 months, one EXE session was cancelled due to sickness among the intervention providers. Only during few holiday periods were EXE sessions offered less than six days a week and some sessions were rescheduled. No MOT sessions were cancelled by the intervention providers. A few MOT sessions were scheduled out of range due to holidays or sickness. However, providers strived to reschedule the

sessions as close to the allocated period as possible (Figure 1). During the process of re-designing the interventions into the online setup due to COVID-19 restrictions, six consecutive EXE sessions were cancelled.

Participants in both intervention groups expressed in the interviews that the intervention accessibility was high. All participants in EXE expressed that the accessibility of the sessions was important to fit the exercise training into their daily lives. Some expressed that the scheduled sessions resulted in a regular exercise routine in which they preferred to attend sessions on the same weekdays. Some participants even scheduled the sessions into their work calendar to indicate to colleagues that they were occupied. For others, the timing of the EXE sessions was a barrier to participation, as it was difficult to fit in to their everyday life and commitments. They were dependent on the frequently offered EXE sessions to devise a more flexible schedule. A woman in EXE mentioned that:

"It (attending exercise sessions) has been a bit difficult to juggle, but being employed as I am, I have quite flexible working hours, and as the sessions were offered on so many different days, I could sort of choose the days when I didn't have to show physically for work" (Participant no. 73, EXE).

Dose received

Throughout the study period, participants randomised to EXE attended on average 1.3 [95% confidence interval, 1.1; 1.5] sessions/week of the recommended 3 from randomisation to delivery. The attendance rate in the online setup of the EXE intervention was 45% higher compared to the attendance rate in the physical setup (online: 1.6 [1.3; 2.0] sessions/week; physical: 1.1 [0.9; 1.4] sessions/week, p=0.027) (Knudsen et al., under review).

During the study period 28% (n=24) the 87 participants in EXE participated on average in 2 or more sessions/week, 32% (n=28) participated on average in 1-1.9 sessions/week, and 40% (n=35) participated on average in less than 1 session/week. Among the 48 participants in who received the physical EXE intervention only, 19% (n=9) attended 2 or more sessions/week, 35% (n=7) attended 1-1.9 session/week, and 46% (n=22) attended less than 1 session/week. Among the 25 women who received the online EXE intervention only, 52% (n=13) attended 2 or more sessions/week, 24% (n=6) attended 1-1.9 sessions/week and 24% (n=) attended less than 1 session/week. The attendance rate in EXE in relation to gestational age is presented in Figure 3.

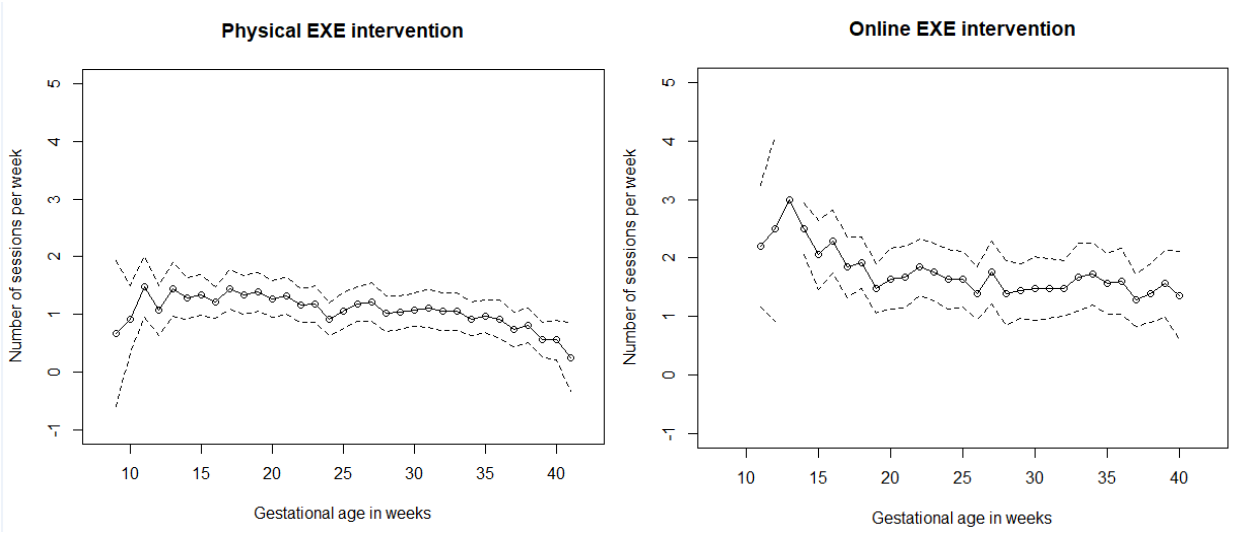

Figure 3. The average weekly number of structured supervised exercise training (EXE) sessions attended in the physical (left) and online (right) intervention, respectively. All participants randomised to EXE (n=87) are included. The attendance was registered from randomisation (~gestational age 10) to delivery (~gestational age 40). Full line, mean number of sessions attended; Dotted lines, 95% confidence interval. The confidence interval at gestational age 13 in the right plot (online interventions) was not calculated because data were essentially constant (all participants attended three times at their GA 13).

Dose received among participants in EXE who were still included and not lost to follow-up did not differ from dose received among all participants randomised to EXE. Throughout the study period,

morning and afternoon sessions seemed to be equally attractive, whereas the Saturday session (a morning gym session) was the most attended during the week (Table 3).

	Mon	Tue	Wed	Thu	Fri	Sat	Gym	Pool	Morning	Afternoon	Overall
Sessions attended, n (%)											
The entire study period	572 (19)	392 (13)	458 (15)	526 (18)	396 (13)	656 (22)	2226 (74)	774 (26)	1444 (48)	1556 (52)	3000 (100)
Before COVID-19	339 (20)	243 (14)	215 (13)	335 (20)	257 (15)	322 (19)	1133 (66)	578 (34)	822 (48)	889 (52)	1711 (57)
During COVID-19	233 (18)	149 (12)	243 (19)	191 (15)	139 (11)	334 (26)	1093 (85)	196 (15)	622 (48)	667 (52)	1289 (43)

Table 3. Distribution of sessions attended (number and percentages) the structured supervised exercise training (EXE) in days of the week, gym or pool, and time of the day. Before COVID-19, from October 2018 to March 11th, 2020; During COVID-19, from March 12th, 2020 to May 2021 due to COVID-19 restrictions. N, number. During the study period participants in EXE overall joined a session 3000 times.

Throughout the study period, participants randomised to MOT attended 5.2 [4.7; 5.7] out of 7 counselling sessions (74%) during their pregnancies. The number of MOT sessions attended did not differ between participants offered physical or online sessions (physical: 5.3 [4.6; 6.0]; online: 5.6 [4.8; 6.4], p=0.970) (Knudsen et al., under review). Sixty four percent of the 87 participants in MOT (n=56) attended six or seven sessions, 13% (n=11) attended four or five sessions and 23% (n=20) attended up to three sessions. More than 80% of participants randomised to MOT attended the first group and the first individual session whereas 57% attended the last group session (Table 4).

	G1	I1	I2	I3	G2	I4	G3
Participants, n (%)	71 (82)	75 (86)	69 (79)	68 (78)	55 (63)	63 (72)	50 (57)

Table 4. Attendance in group and individual sessions in MOT during the study period. G, group session; I, individual session; MOT, motivational counselling on physical activity; N, number.

The average percentage of attendance in group and individual sessions were 67% and 79%, respectively. Among participants still included in MOT, more than 80% attended the first group and all individual sessions and approximately 70% attended group session 2 and 3. For participants still included in MOT, the average percentage of attendance in group and individual sessions was 76% and 89%, respectively. Dose received among participants in MOT who were still included and not lost to follow-up differed from dose received among all participants randomised to MOT.

In both intervention groups, participants expressed in the interviews that being part of a group was valued, but that it was seen only as a fun and enjoyable factor and not to network or build new relationships. To some degree, participants in EXE expressed that it was difficult to participate in the sessions due to work, logistics, and family commitments in their everyday life, which they to a larger extent than usual needed to organise. They experienced that in relation to some family activities they were less present than they used to be and wanted to be. In addition, they were more dependent than usual on their partner, for example, to pick up and drop off their children at day care or school etc. and accompany them to leisure activities due to scheduled EXE sessions. A participant in EXE, aged 30 years and with a three-year old child, described how she and her husband organised everyday activities:

"Well, we need to do some planning. For example, I often attend on Wednesday afternoons, and my daughter has also started gymnastics - so they (husband and child) also come home late and we will eat leftovers that day" (Participant no. 117, EXE).

Furthermore, it was difficult for participants in EXE to take part in family routines such as evening meals or preparation of these on days with an afternoon EXE session. For some participants, this led to a sense of guilt for not being present in family matters. However, participating in EXE sessions was perceived as a good opportunity to focus on oneself and, despite spending less time with the

family, the women experienced increased energy to take care of older children and everyday chores at other times. On a purely practical level, participants in EXE expressed that they needed a car to be able to reach the gym or swimming pool. A 31-year old woman explained how attendance was hindered:

"I didn't really think transportation would matter, but it did, because we only have one car ... I had to drop off my child beforehand, it just didn't add up. I actually invested in a travel card for the train, but it was so much easier when the car was available" (Participant no. 87, EXE).

Commuting back and forth to the EXE sessions was by some of the participants in EXE not living near the training facilities, perceived as time heavy and as a barrier towards participation. In contrast, commuting was expressed as one of the most significant changes in the everyday life among a large part of participants in MOT. Instead of driving between their workplace and home as they normally would, they incorporated active commuting. In addition, the participants in MOT incorporated more PA into already existing activities and added new activities that also involved family members. Participants in MOT expressed that it was important for them not to let their PA level limit their presence in family matters. A woman who was unemployed tried to schedule her exercise routines by separating them from family time:

"I wanted to be physically active while my boyfriend was at work and my daughter was at day care, so in that way I don't think it (her being physically active) had any impact on our daily lives" (Participant no. 71, MOT).

In contrast, a woman with two older children combined family time with her being physically active:

"My children do gymnastics twice a week, and instead of them biking alone, I bike with them. They find it very nice. Additionally, my husband and I have had a few more evening walks together just

the two of us while the kids were at home. It was really nice because I've also needed to "achieve" some more steps (on the tracker). My husband just said: "Okay, then I'll come with you"" (Participant no. 109, MOT).

Notably, it seemed like participation in PA in MOT was perceived as easier to fit into everyday life, and that it caused less conflicts than what was perceived among participants in EXE.

Mechanisms of impact

In general, participants in both intervention groups expressed in the interviews that they valued the interventions and appreciated being part of a research study. The participants expressed that they were able to plan their own working hours, which allowed them to interact with the interventions. A mechanism of impact was that the scheduled EXE sessions represented a *commitment* that participants in EXE felt responsible for keeping. It resulted in participants not having to continually "renegotiate", either with their families or with themselves, to prioritise time for PA in their daily lives. Participants in EXE expressed that having intervention providers and other EXE participants waiting for them had a high impact on their commitment to the intervention and was a motivator for being physically active:

"I'm a very dutiful person, so when something is in my calendar and I've said it's a deal, well, it's a deal. I'm not so dutiful when it comes to my own obligations to myself. But when I say I'm going to show up, I show up." (Participant no. 73, EXE).

In contrast, participants in MOT expressed that they felt self-determined towards PA and how to structure and organise PA on their own while supervised and supported by the intervention providers. A *perception of empowerment* was one of the most motivating and important mechanisms of impact for participation in MOT and for their PA level and intervention

maintenance. As participants in EXE, they expressed a great ability to independently structure their everyday life, which was essential for participation:

"I have a job where I have a lot of flexibility, so when I had to go in for a counselling session, I've just taken time off and worked at another time" (Participant no. 124, MOT).

Another mechanism of impact was the *perceptions of PA* which were notably different between the two groups. Participants in EXE considered PA to be an event that took place at a specific time point. Once they had participated in an EXE session, PA was not considered integrated in the remaining day:

"Well, I think (when attending an exercise session), I can tick that one off. Then I have kind of been active today. It was like one of those things that I had on my agenda" (Participant no. 103, EXE).

It appeared that participants in EXE separated everyday activities from what they perceived as actual exercise and distinguished between PA intensities. They found the sessions to be fruitful and valuable, but at the same time they noted the low degree of autonomy regarding the specific content of the sessions. For example, some of the participants in EXE found the 30 min session on the stationary bike (the first part of the 1-hour session in the original setup) monotonous and bland. However, their motivation was that stationary biking was the best activity to increase the heart rate to the required level when they felt heavier which made them continue. Participants in MOT expressed that PA of all kinds was considered valid, regardless of intensity. A woman expressed it like this:

"Exercise doesn't have to be me going to the gym three times a week or me going for that run like everybody else does. This thing about exercise, it can be many things. It can also be that I just take the stairs 10 times or that I just walk faster with the pram now that I'm out walking anyway. So, I

think it (PA) just became more simplified. That it doesn't have to be so difficult" (Participant no. 133, MOT).

The different perceptions of PA were also expressed in the way that the participants referred to the mental and physical reactions and changes they experienced. Participants in EXE focused particularly on bodily capacities, changes and appearance:

"You can tell from my body that I've been training hard … I can see it in my posture and just things like thighs and glutes and arms and stuff. They were maybe just a bit more untrained [before]" (Participant no. 81, EXE)

and

"I think it has been amazing to feel that I have become stronger" (Participant no. 86, EXE).

Participants in MOT expressed a somewhat broader perception of PA effects as they found themselves with greater insight and understanding of themselves being pregnant and with increased mental health and well-being:

"I've really felt good about my body in this pregnancy and I think that's so great. I think it's largely because I've gotten to know my body and I'm in such good condition" (Participant no. 124, MOT) and *"I think it (being a part of the intervention) had an impact on my well-being in general, including my mental well-being. Because I can feel my mood gets better, when I exercise* (Participant no. 74, MOT).

Discussion

This process evaluation demonstrated that the FitMum study *reached* a selected group of pregnant women with a high educational level and flexibility in their working and everyday life although it per protocol was aimed to include participants representative for the general pregnant Danish

population (Knudsen et al., under review). The participants had altruistic and personal reasons to participate in the FitMum study and a general interest in their own and their unborn child's health, which, in line with previous studies, enabled a prioritisation of PA in their everyday life (11,31). Notably, the participants perceived being physically active as a prerequisite to an uncomplicated pregnancy and delivery and expressed a potential self-blame if any complications occurred. A paradox arose between a desire for being physically active and a sense of guilt for spending less time with their family. It was identified that the interventions (*dose*) were well *delivered*, and that implementation *fidelity* was high in both interventions applied in the original setup with physical attendance and in the altered, online setup implemented during the COVID-19 pandemic. A low and varying *dose* of the EXE intervention *received*, especially in the physical setup, might be explained by the fact that the attendance in EXE relied on high everyday flexibility among participants. During the COVID-19 restriction, the everyday life changed radically with positive consequences for the dose received among participants in EXE. The high intervention accessibility was important for the participants to adapt PA into their everyday life. Baseline characteristics of the participants and their high everyday autonomy interacted more than anticipated with especially the *dose received* in EXE and thus provided insights into unanticipated contextual factors.

This process evaluation showed that the interventions and the way participants were influenced by them affected the *mechanisms of impact* differently in the two intervention groups. This was reflected, among other things, in a discrepancy in the perception of PA among participants in the two intervention groups. With the Self-Determination Theory (32) as a theoretical basis, the approach was that behaviour is complex and that people are rarely driven by either intrinsic or extrinsic motivation. Behaviour often tends to lie in the middle of either pure self-determination driven by pleasure and interest (intrinsic) and at the other end of the continuum the non-self-determined behaviour performed out of necessity or obligation (extrinsic). In brief, the theory posits

that people are driven by connection to others, competence to perform a given task, and autonomy of one's behavior to achieve psychological growth. As an example, participants in EXE experienced an extrinsic motivation because of the experienced commitment to the intervention, which fuelled an intrinsic motivation supported by the experienced ability to develop a routine for attending the sessions as well as the perceived bodily changes. As lack of time and fatigue are commonly cited barriers towards PA in pregnancy, participation in structured exercise may improve general PA behaviour (11). Participants in EXE felt a *connection* to the intervention whereas participants in MOT expressed a high *perceived competence and autonomy* towards PA, expressed as intrinsic motivators such as the high *perception of empowerment* towards PA. Conversely, extrinsic motivators including *commitment* to others and to the study itself were expressed by participants in both interventions.

A systematic review (21) on issues of internal and external validity in interventions to improve PA during pregnancy found that reach and effectiveness of the interventions were well reported in randomised controlled trials and quasi-experimental studies with a comparator group included. However, information on for example dose, representativeness of participants and setting were less commonly reported. To the best of our knowledge, few process evaluations of PA interventions during pregnancy have been performed, and none of them had a scope directly comparable to the present study (22,23). The process evaluations of the pilot study of Vitamin D and Lifestyle Intervention (DALI) (22) and the UK Pregnancies Better Eating and Activity Trial (UPBEAT) (23) focused on lifestyle interventions including PA to prevent gestational diabetes mellitus among overweight and obese pregnant women. Findings from the process evaluations of these studies (22,23) coincided with some of the findings in the present study and revealed that practicalities often interfered with regular attendance in sessions even though participants claimed that they were willing to attend. Moreover, in the DALI study it was revealed that participation was very time-

consuming for the women, which led to lower participation rates (22). Few effect evaluations of interventions comparable to the FitMum study included process evaluation dimensions such as reach and dose. Those dimensions were often reported in connection with the presentation of participant flowcharts and attendance rates (17,33–35). Wang et al. (35) reported a high attendance rate in a gym-based intervention, however, no mechanisms of impact were reported except from a high predefined limit of intervention adherence that might have influenced the attendance. In contrast, Oostdam et al. (17) reported a low attendance rate in a gym-based intervention which was to some degree explained by a low intervention accessibility. For future perspectives the mechanisms of impact as commitment, perception of empowerment and perception of PA as well as the paradox between prioritising PA and family and the need of a flexible everyday life need to be considered. When implementing PA interventions, the "efficacy paradox" should be paid attention (36). This means that the most effective intervention, as studied under optimal conditions, might not be the most effective intervention, when applied in a real-world setting. Less effective interventions may have a greater potential of implementation in people's everyday life and environments.

Strength and limitations

The main strength of the study was the application of a mixed methods design (24), which provided a comprehensive insight into how the two complex PA interventions were implemented and an explanatory interpretation of how they produced changes. The application of the Medical Research Council process evaluation framework (19) enabled us to report findings of the process evaluation dimensions and to illustrate facilitators and barriers influencing the intervention implementation and effectiveness. Moreover, the framework supported an understanding of context and potential mechanisms of impact related to the effects of the FitMum study on PA. A limitation was that the unintended alterations of the intervention design due to the COVID-19 restrictions were only quantitatively covered. While the attendance rate in EXE was significantly higher in the online

intervention compared to the physical, a qualitative insight investigating any reasons could provide important knowledge. Another limitation was that process evaluation data were among others collected by one of the intervention providers (SdPK). However, this person's in-depth knowledge of the structure and content of the interventions supported a comprehensive process evaluation.

Conclusion

This mixed methods study demonstrated that participants *reached* in the FitMum study had a higher everyday life autonomy and educational level compared to the general population. The PA interventions (*dose*) were well *delivered* with high *fidelity* in the original physical intervention setup as well as in the altered online intervention setup during the COVID-19 restrictions. Although intervention accessibility was expressed as high, the low and varying *dose received* in EXE may be a result of the fact that participation should not be at the expense of time spent with their family. *Mechanisms of impact* comprised among participants in EXE a commitment to the intervention and a flexible everyday life, whereas a perception of empowerment towards PA was essential among participants in MOT. The perception of PA was different in the two intervention groups as participants in EXE considered PA to be a time constrained activity, whereas participants in MOT thought of PA as everyday activities without paying attention to PA intensity. During the online EXE setup, the dose received increased compared to the physical EXE setup. For future perspectives, prenatal PA interventions might benefit from integrating a combination of physical attendance at one-hour structured supervised exercise sessions and frequent 30-min home-based, online supervised exercise sessions to increase the dose received among pregnant women. In addition, an awareness of PA perception, PA empowerment and commitment to others should be considered.

List of abbreviations

CON: Standard care; EXE: Structured supervised exercise training; Min: Minutes; MOT: Motivational counselling on physical activity; MVPA: Moderate-to-vigorous-intensity physical activity; PA: Physical activity

Availability of data and materials

The Danish Data Protection Agency has not approved data sharing.

Competing interests

The authors declare that they have no competing interests.

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Authors' contribution

SdPK and HTM developed the study design. SdPK, CBR and ADJ collected quantitative data assisted by SAA, research assistants and master students. SdPK conducted the interviews with contribution from ADJ, a research assistant and a master student. SdPK performed statistical and qualitative analyses with contribution from SAA and JBø, respectively. SdPK interpreted data and wrote the manuscript supervised by HTM. BS initiated and directed the FitMum study, and EL was the clinical trial manager and supervised the interventions in collaboration with JMB, TDC, SM and BS. All authors read, contributed to, and approved the final version of the manuscript.

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Additional files

Additional file 1: Interview guide

References

1. Fair F, Soltani H. A meta-review of systematic reviews of lifestyle interventions for reducing gestational weight gain in women with overweight or obesity. Obesity Reviews. 2021;1–21.

2. Ruchat SM, Mottola MF, Skow RJ, Nagpal TS, Meah VL, James M, et al. Effectiveness of exercise interventions in the prevention of excessive gestational weight gain and postpartum weight retention: A systematic review and meta-analysis. British Journal of Sports Medicine. 2018;52(21):1347–56.

3. Díaz-Burrueco JR, Cano-Ibáñez N, Martín-Peláez S, Khan KS, Amezcua-Prieto C. Effects on the maternal-fetal health outcomes of various physical activity types in healthy pregnant women. A systematic review and meta-analysis. European Journal of Obstetrics & Gynecology and Reproductive Biology. 2021 Jul;262:203–15.

4. Hayes L, McParlin C, Azevedo L, Jones D, Newham J, Olajide J, et al. The Effectiveness of Smoking Cessation, Alcohol Reduction, Diet and Physical Activity Interventions in Improving Maternal and Infant Health Outcomes: A Systematic Review of Meta-Analyses. Nutrients. 2021;13(1036):1–31.

5. Mottola MF, Davenport MH, Ruchat SM, Davies GA, Poitras VJ, Gray CE, et al. 2019

Canadian guideline for physical activity throughout pregnancy. British Journal of Sports Medicine. 2018;52(21):1339–46.

6. Physical Activity Guidelines Advisory Committee Scientific Report. 2018 Physical Activity Guidelines Advisory Committee. Washington, DC: US Department of Health and Human Services. 2018;(F8-1).

7. Bhattacharjee J, Mohammad S, Adamo KB. Does exercise during pregnancy impact organs or structures of the maternal-fetal interface? Tissue and Cell. 2021 Oct 1;72:1–14.

8. Díaz-Burrueco JR, Cano-Ibáñez N, Martín-Peláez S, Khan KS, Amezcua-Prieto C. Effects on the maternal-fetal health outcomes of various physical activity types in healthy pregnant women. A systematic review and meta-analysis. European Journal of Obstetrics & Gynecology and Reproductive Biology. 2021;262:203–15.

9. Morales-Suárez-Varela M, Clemente-Bosch E, Peraita-Costa I, Llopis-Morales A, Martínez I, Llopis-González A. Maternal Physical Activity During Pregnancy and the Effect on the Mother and Newborn: A Systematic Review. Journal of Physical Activity and Health. 2020;1–18.

10. Sánchez-Polán M, Franco E, Silva-José C, Gil-Ares J, Pérez-Tejero J, Barakat R, et al. Exercise During Pregnancy and Prenatal Depression: A Systematic Review and Meta-Analysis. Frontiers in physiology. 2021;12:1–13.

11. Harrison AL, Taylor NF, Shields N, Frawley HC. Attitudes, barriers and enablers to physical activity in pregnant women: a systematic review. Journal of Physiotherapy. 2018;64(1):24–32.

12. Coll CVN, Domingues MR, Gonçalves H, Bertoldi AD. Perceived barriers to leisure-time

physical activity during pregnancy: A literature review of quantitative and qualitative evidence. Journal of Science and Medicine in Sport. 2017;20(1):17–25.

13. Oude Rengerink K, Logtenberg S, Hooft L, Bossuyt PM, Mol BW. Pregnant womens' concerns when invited to a randomized trial: A qualitative case control study. BMC Pregnancy and Childbirth. 2015;15(1).

14. Pearce EE, Evenson KR, Downs DS, Steckler A. Strategies to Promote Physical Activity During Pregnancy. Vol. 7, American Journal of Lifestyle Medicine. NIH Public Access; 2013. p. 38–50.

15. James P, Morgant R, Merviel P, Saraux A, Giroux-Metges MA, Guillodo Y, et al. How to promote physical activity during pregnancy : A systematic review. Journal of Gynecology Obstetrics and Human Reproduction. 2020;49(9).

16. Seneviratne SN, Jiang Y, Derraik JGB, McCowan LME, Parry GK, Biggs JB, et al. Effects of antenatal exercise in overweight and obese pregnant women on maternal and perinatal outcomes: A randomised controlled trial. BJOG: An International Journal of Obstetrics and Gynaecology. 2016;123(4):588–97.

17. Oostdam N, Van Poppel MNM, Wouters MGAJ, Eekhoff EMW, Bekedam DJ, Kuchenbecker WKH, et al. No effect of the FitFor2 exercise programme on blood glucose, insulin sensitivity, and birthweight in pregnant women who were overweight and at risk for gestational diabetes: Results of a randomised controlled trial. BJOG: An International Journal of Obstetrics and Gynaecology. 2012;119(9):1098–107.

18. Roland CB, Knudsen S de P, Alomairah SA, Andersen AD, Bendix J, Clausen TD, et al. Structured supervised exercise training or motivational counselling during pregnancy on

physical activity level and health of mother and offspring: FitMum study protocol. BMJ Open. 2021;11(3):1–11.

19. Moore G et al. Process evaluation of complex interventions: Medical Research Council guidance. 2015;

20. Skivington K, Matthews L, Simpson SA, Craig P, Baird J, Blazeby JM, et al. A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. The BMJ. 2021;374.

21. Craike M, Hill B, Gaskin CJ, Skouteris H. Interventions to improve physical activity during pregnancy: a systematic review on issues of internal and external validity using the RE-AIM framework. BJOG: An International Journal of Obstetrics and Gynaecology. 2017;124(4):573–83.

22. Jelsma JGM, Simmons D, Gobat N, Rollnick S, Blumska K, Jans G, et al. Is a motivational interviewing based lifestyle intervention for obese pregnant women across Europe implemented as planned? Process evaluation of the DALI study. BMC Pregnancy and Childbirth. 2017;17(1):293.

23. Poston L, Briley AL, Barr S, Bell R, Croker H, Coxon K, et al. Developing a complex intervention for diet and activity behaviour change in obese pregnant women (the UPBEAT trial); assessment of behavioural change and process evaluation in a pilot randomised controlled trial. BMC pregnancy and childbirth. 2013;13(1):148.

24. Creswell, J.W., Clark VL. Designing & conducting mixed methods research + the mixed methods reader. Designing & conducting mixed methods research + the mixed methods reader. 2017;1(2):24–7.

25. Kvale S, Brinkmann S. Interview: det kvalitative forskningsinterview som håndværk. Kvale S, Brinkmann S, editors. Hans Reitzels Forlag; 2015.

26. Othman S, Steen M, Fleet J-A. A sequential explanatory mixed methods study design: An example of how to integrate data in a midwifery research project. Journal of Nursing Education and Practice. 2020;11(2):75.

27. Fetters MD, Curry LA, Creswell JW. Achieving integration in mixed methods designs - Principles and practices. Health Services Research. 2013;48(6 PART2):2134–56.

28. QSR International Pty Ltd., NVivo. 2020.

29. Malterud K. Kvalitative forskningsmetoder for medisin og helsefag. Universitetsforlaget; 2017.

30. Min-Mave.dk – Danmarks største site for gravide og småbørnsforældre [Internet]. Available from: https://min-mave.dk/

31. Rockliffe L, Peters S, Heazell AEP, Smith DM. Factors influencing health behaviour change during pregnancy: a systematic review and meta-synthesis. Health Psychology Review. 2021;15(4):613–32.

32. Ryan R, Deci E. Self-determination theory and the facilitation of intrinsic motivation. American Psychologist. 2000;55(1):68–78.

33. Seneviratne S, Jiang Y, Derraik J, McCowan L, Parry G, Biggs J, et al. Effects of antenatal exercise in overweight and obese pregnant women on maternal and perinatal outcomes: a randomised controlled trial. BJOG: An International Journal of Obstetrics & Gynaecology. 2016;123(4):588–97.

34. Leung Hui A, Back L, Ludwig S, Gardiner P, Sevenhuysen G, Dean HJ, et al. Effects of lifestyle intervention on dietary intake, physical activity level, and gestational weight gain in pregnant women with different pre-pregnancy Body Mass Index in a randomized control trial. BMC Pregnancy and Childbirth. 2014;14(331):1–9.

35. Wang C, Wei Y, Zhang X, Zhang Y, Xu Q, Sun Y, et al. A randomized clinical trial of exercise during pregnancy to prevent gestational diabetes mellitus and improve pregnancy outcome in overweight and obese pregnant women. American Journal of Obstetrics and Gynecology. 2017;1–30.

36. Zhang W, Doherty M. Efficacy paradox and proportional contextual effect (PCE). Clinical Immunology. 2018;186:82–6.

Additional file:

Interview guide

Inclusion and participation in the FitMum trial:

When you were enrolled in the FitMum trial, you were asked why you would like to participate. Try to answer the same questions now (no matter your previous answer).

Can you tell me about your thoughts on health and physical activity during pregnancy?

Why and for whom was and is it important to participate?

Did you discuss your participation with your partner or others before you made the decision to attend? If so, what impact did their attitude have on your participation?

What was it like for you to sign up for a project that was only for women who exercised less than an hour a week?

What thoughts did you have before and during participation about difficulties/barriers to participation?

Can you tell me about the specific reactions you received from others (partner, family, friends, colleagues) to your participation?

How were you greeted by the FitMum staff when you were enrolled and during the subsequent visits? What influence did this have on your participation?

Please describe any changes to you and your family's everyday life (mainly in terms of physical activity and time used) as a result of your participation in the FitMum trial.

Perception of the content in structured supervised exercise training (EXE) or motivational counselling on physical activity (MOT), physical activity in everyday life, and barriers and enablers towards physical activity:

Please describe a typical day and week while being a part of the FitMum trial.

Please describe a typical day when you attended an intervention session (concrete examples of what you did to participate).

Please describe an intervention session. How did the session proceed, and what was your perception of the session?

What did you do specifically to make it possible for you to participate? (work, family, cooking, shopping, who helped you and how)

What barriers did you perceive to participating (intervention accessibility, content, etc.)?

What could have made it easier to participate?

Please describe your thoughts and perceptions about physical activity in your everyday life. Is there a difference from before pregnancy to now?

In concrete terms, what have you gained from being a part of the structured supervised exercise training group?

Importance of physical activity during pregnancy:

Why/why not did you exercise during your present pregnancy?

What motivated you to be physically active?

Did your motivation toward physical activity change during your enrolment in the FitMum trial? Please describe how.

What is important in your everyday life for you to be able to be physically active? (family, support, time spend, leisure time, etc.)

How did your participation in the FitMum trial influence your physical activity level?

Please describe hypothetically how your everyday life (in terms of physical activity) would have been if you had not been enrolled in the FitMum trial.

Do you have anything to add? Thank you very much