UNIVERSITY OF COPENHAGEN
FACULTY OF HEALTH AND MEDICAL SCIENCE

# Effect of physical activity interventions during pregnancy on physical activity levels, sedentary time, and sleep

A PhD project based on results from the FitMum randomised controlled trial

## PhD Thesis

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**List of Tables and Figures**

## The thesis is based on the following four manuscripts:

**Paper 1**

Roland, C. B.*, Knudsen, S. P.*, **Alomairah, S. A**.*, Andersen, A. D., Bendix, J.M, Clausen, T. D., Molsted, S., Jensen, A. K., Teilmann, G., Jespersen, A. P., Larsen, J. E., Hall, G. V., Andersen, E., Barrès, R., Mortensen, O. H., Maindal, H. T., Tarnow, L., Løkkegaard, E., & Stallknecht, B. (2021). Structured supervised exercise training or motivational counseling during pregnancy on physical activity level and health of mother and offspring: FitMum study protocol. BMJ Open, 11(3), e043671. https://doi.org/10.1136/bmjopen-2020-043671

**Contributed equally. This paper is also included in the PhD theses of Caroline Borup Roland and Signe de Place Knudsen.*

**Paper 2**

**Alomairah, S. A**., Knudsen, S. P, Roland, C. B., Hergel, I. M, Molsted, S., Clausen, T. D., Løkkegaard, E., Bendix, J.M., Maddison, R., Löf, M., Larsen, J. E, van Hall, G, & Stallknecht, B. (2023). Methods to Estimate Energy Expenditure, Physical Activity, and Sedentary Time in Pregnant Women: A Validation Study Using Doubly Labeled Water. Journal for the Measurement of Physical Behaviour. Advance online publication. https://doi.org/10.1123/jmpb.2022-0033

**Paper 3**

Knudsen, S. P.*, **Alomairah, S. A***., Roland, C. B., Jessen, A. D., Hergel, I. M., Clausen, T. D., Larsen, J. E., van Hall, G., Jensen, A. K., Molsted, S., Bendix, J. M., Løkkegaard, E., & Stallknecht, B. (2022). Effects of Structured Supervised Exercise Training or Motivational Counseling on Pregnant Women's Physical Activity Level: FitMum - Randomized Controlled Trial. Journal of Medical Internet Research, 24(7), e37699. https://doi.org/10.2196/37699

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**Paper 4**

**Saud Abdulaziz Alomairah**, Signe de Place Knudsen, Caroline Borup Roland, Stig Molsted, Tine D. Clausen, Jane M. Bendix, Ellen Løkkegaard, Andreas Kryger Jensen, Jakob Eg Larsen, Poul Jennum, & Bente Stallknecht. Effects of two physical activity interventions on sleep and sedentary time in pregnant women. *Under review in the International Journal of Environmental Research and Public Health.*

**Published papers not included in this thesis but written as a co-author.**

1- Krøner, F. H., Knudsen, S. D. P., Roland, C. B., **Alomairah, S. A**., & Molsted, S. Validity and reliability of the Danish version of the pregnancy physical activity questionnaire to assess levels of physical activity during pregnancy. The Journal of Maternal-Fetal & Neonatal Medicine, 1-7 (2020). https://doi.org/10.1080/14767058.2020.1856807

2- De Place Knudsen, S., Borup Roland, C., **Abdulaziz Alomairah, S**., Dsane Jessen, A., Molsted, S., Clausen, T., Løkkegaard, E., Stallknecht, B., Bønnelycke, J., Bendix, J.M, & Terkildsen Maindal, H. Physical activity in pregnancy: a mixed methods process evaluation of the FitMum randomised controlled trial interventions. BMC Public Health 22, 2283 (2022). https://doi.org/10.1186/s12889-022-14717-1

# Summary

Physical activity (PA) during pregnancy is associated with positive health outcomes for mothers and babies. Many health organisations worldwide recommend that pregnant women with no medical reasons preventing PA engage in moderate-intensity physical activity for at least 150 minutes per week. Yet, few pregnant women reach these recommendations. In Denmark, the health authority recommends moderate intensity PA of 30 minutes/day (210 minutes/week) for healthy pregnant women. Still, like the global trend, few pregnant women in Denmark reach this recommendation. Additionally, pregnancy induces physiological and psychological changes that might interrupt the physical behaviour of pregnant women. For example, compared to the general population, pregnant women sleep less and spend more time sedentary. Increasing PA during pregnancy might reduce sedentary time (SED) and improve sleep. Nevertheless, the knowledge about the most effective strategies to increase PA among pregnant women, decrease SED, and improve sleep is limited. Moreover, without the "perfect" tool to measure physical behaviour (PA, SED, and sleep), there is a need to combine and compare subjective and objective methods for assessing physical behaviour during pregnancy.

This PhD thesis aims to 1) test the effect of offering two PA interventions on PA levels during pregnancy and 2) explore the impact of these two PA interventions on SED and sleep. The scientific work presented here is based on the randomised controlled trial (RCT), the FitMum study. This thesis contains the following papers: **Paper 1** describes the design, procedures, and interventions of the FitMum study. **Paper 2** investigated and compared the validity of the methods used to measure PA and SED in the FitMum study. **Paper 3** presented the effect of two PA interventions on moderate-to-vigorous intensity PA (MVPA; primary outcome) and other measures of PA, and **Paper 4** explored the impact of two PA FitMum interventions on SED and sleep quality and quantity.

From October 2018 to May 2021, the FitMum study was conducted at the Department of Gynaecology and Obstetrics at Nordsjaellands Hospital in Hillerod, Denmark's capital region. On March 11, 2020, the restrictions in Denmark due to the COVID-19 pandemic began, and the interventions changed to online sessions. In total, 219 pregnant women were randomly assigned to one of three groups: a control group (CON) receiving standard care (n=45), a group receiving structured supervised exercise training (EXE) offered three times per week throughout pregnancy (n=87), and a group receiving motivational counselling on PA (MOT) offered seven times during pregnancy; four individual and three group counselling sessions

(n=87). PA, SED and sleep were measured by both subjective (questionnaires) and objective methods (commercial activity tracker and the doubly labelled water (DLW)) (**Paper 1**).

The validity of the commercial activity tracker and the Danish pregnancy PA questionnaire (PPAQ-DK) were compared and validated against the DLW in **Paper 2.** We found that the activity tracker's energy expenditure estimations agreed better with DLW than with the PPAQ-DK. Total energy expenditure from the activity tracker and DLW had a reasonable correlation; however, neither PA energy expenditure nor PA level did. The activity tracker measured lower PA and higher SED than the PPAQ-DK throughout pregnancy. Although the activity tracker performed better than the PPAQ-DK, both overestimated PA compared to DLW.

The effect and the primary outcome of the FitMum study, which is MVPA, and complementary PA, were investigated in **Paper 3**. When measured objectively by the activity tracker, pregnant women receiving EXE achieved more MVPA than those offered CON. There were no differences in MVPA between pregnant women in MOT and CON or EXE and MOT. However, women in MOT subjectively reported an increased vigorous PA level. MVPA was sustained throughout pregnancy at the same level in all three groups yet did not reach the recommended 210 minutes/week. Finally, during COVID-19 restrictions, MVPA was not affected by shifting the interventions to online, but exercise participation increased in EXE.

In **Paper 4**, we conducted a secondary analysis to explore the effect of the FitMum interventions on SED and sleep quality and quantity. The results revealed that when sleep was measured subjectively, pregnant women in EXE had better sleep quality and less SED than pregnant women in CON. When measured objectively by the activity tracker, there were no differences between the groups but a clear tendency toward more SED and less sleep time as the pregnancy progressed. In addition, EXE who received the online intervention during COVID-19 restrictions had more SED than those who received the physical intervention before COVID-19.

In conclusion, increasing PA during pregnancy is achievable as offering EXE was more effective than CON in increasing MVPA. The impact achieved by EXE in MVPA was detected objectively by the activity tracker but reflected subjectively on less SED and better sleep quality. Pregnant women in the FitMum study increased their SED and decreased sleep time, which compromised toward the end of pregnancy as measured objectively by the activity tracker. Although we observed only a modest increase in PA levels in the FitMum study, increasing PA may effectively reduce SED and enhance sleep quality during pregnancy. In EXE, COVID-19 restrictions and online interventions increased exercise participation and maintained MVPA levels but increased SED. Physical and online exercise interventions during pregnancy that reduce SED might be a good strategy and should be investigated more. Measuring physical activity, sedentary

time, and sleep quality and quantity during pregnancy is complicated. No perfect measuring tool exists but combining subjective and objective tools might give a comprehensive picture.

# Summary in Danish

Fysisk aktivitet under graviditeten er forbundet med positive sundhedseffekter for mødre og spædbørn. Mange sundhedsorganisationer verden over anbefaler gravide kvinder uden kontraindikationer at være fysisk aktive i mindst 150 minutter om ugen ved moderat intensitet. Alligevel er det kun få gravide kvinder, der opfylder disse anbefalinger. I Danmark anbefaler Sundhedsstyrelsen, at raske gravide kvinder er fysisk aktive ved moderat intensitet i 30 minutter/dag (210 minutter/uge). I lighed med den globale tendens er det dog kun få gravide kvinder i Danmark, der er fysisk aktive svarende til denne anbefaling. Graviditeten medfører fysiologiske og psykologiske ændringer, som kan påvirke kvindens adfærd. Sammenlignet med den almindelige befolkning sover gravide kvinder mindre og tilbringer mere stillesiddende tid; disse to adfærdsmønstre forværres, efterhånden som graviditeten skrider frem. Øget fysisk aktivitet under graviditeten kan reducere den stillesiddende tid og forbedre søvnen. Ikke desto mindre er der kun begrænset viden om de mest effektive strategier til at øge det fysiske aktivitetsniveau blandt gravide kvinder, mindske den stillesiddende tid og forbedre søvnen. Da der desuden ikke findes det "perfekte" værktøj til måling af fysisk adfærd (fysisk aktivitet, stillesiddende tid og søvn), er der behov for at kombinere og sammenligne subjektive og objektive metoder til måling af fysisk adfærd under graviditeten.

Denne ph.d.-afhandling har til formål at 1) teste effekter af at tilbyde to forskellige træningsinterventioner målt på det fysiske aktivitetsniveau under graviditeten og 2) undersøge virkninger af disse interventioner målt på stillesiddende tid og søvn. Det videnskabelige arbejde i denne ph.d.-afhandling er baseret på et randomiseret kontrolleret studie, FitMum, og indeholder følgende artikler: I **artikel 1** beskrives design, procedurer og interventioner i FitMum. I **artikel 2** undersøges og sammenlignes validiteten af de metoder, der blev brugt til at bestemme fysisk aktivitet og stillesiddende tid. **Artikel 3** præsenterer effekterne af FitMum interventionerne på det fysiske aktivitetsniveau, og **artikel 4** udforsker indvirkningerne af FitMum interventionerne på stillesiddende tid og søvn.

Fra oktober 2018 til maj 2021 blev FitMum studiet gennemført på Gynækologisk Obstetrisk Afdeling på Nordsjællands Hospital i Hillerød. Den 11. marts 2020 begyndte restriktionerne i Danmark på grund af COVID-19-pandemien, og interventionerne blev ændret til online sessioner. I alt blev 219 gravide kvinder tilfældigt tildelt én af tre grupper: en kontrolgruppe (CON), der modtog almindelig svangreomsorg (n=45), en gruppe der modtog struktureret superviseret holdtræning (EXE), der blev udbudt tre gange om ugen i løbet af graviditeten (n=87), og en gruppe der modtog motiverende rådgivning om fysisk aktivitet (MOT), der blev tilbudt syv

gange i løbet af graviditeten; fire individuelle og tre gruppesamtaler (n=87). Fysisk aktivitet, stillesiddende tid og søvn blev målt ved subjektive (spørgeskemaer) og objektive målinger (kommerciel aktivitetstracker og dobbeltmærket vand) (**artikel 1**).

Validiteten af aktivitetsmåleren og det danske spørgeskema om fysisk aktivitet under graviteten er blevet valideret i forhold til dobbeltmærket vand (**artikel 2**). Aktivitetsmåleren og spørgeskemaet om fysisk aktivitet i graviditeten blev sammenlignet. Vi fandt, at aktivitetsmålerens estimater af energiforbruget stemte mere overens med dobbeltmærket vand end med spørgeskemaet om fysisk aktivitet i graviditeten. Det totale energiforbrug fra aktivitetsmåleren og dobbeltmærket vand havde en rimelig korrelation. Det havde dog hverken energiforbruget forbundet med fysisk aktivitet eller det fysiske aktivitetsniveau. Aktivitetsmåleren angav et lavere fysisk aktivitetsniveau og mere stillesiddende tid under hele graviditeten end spørgeskemaet om fysisk aktivitet i graviditeten. Selv om aktivitetsmåleren fungerede bedre end spørgeskemaet, overvurderede begge målemetoder det fysiske aktivitetsniveau sammenlignet med dobbeltmærket vand.

I **artikel 3** blev effekterne af de to interventioner målt på fysisk aktivitet ved moderat til høj intensitet (det primære resultat af FitMum) og andre aspekter af fysisk aktivitetsniveau blev undersøgt. De objektive målinger med aktivitetsmåleren viste, at gravide kvinder, der fik tilbudt EXE, var mere fysisk aktive ved moderat til høj intensitet end de, der fik tilbudt CON. Der var ingen forskelle i MOT sammenlignet med CON og ej heller mellem EXE og MOT. De, der deltog i MOT, rapporterede dog subjektivt øget fysisk aktivitet ved høj intensitet. Desuden blev fysisk aktivitet ved moderat til høj intensitet i alle tre grupper opretholdt på samme niveau under hele graviditeten, men nåede dog ikke op på de anbefalede 210 minutter om ugen. Endelig blev fysisk aktivitet ved moderat til høj intensitet under COVID-19-restriktionerne ikke påvirket af, at interventionen blev leveret online. Træningsdeltagelsen i EXE steg under COVID-19 sammenlignet med deltagelsen ved fysisk fremmøde.

I **artikel 4** gennemførte vi en sekundær analyse for at undersøge effekter af FitMum-interventionerne på stillesiddende tid og søvn. De subjektive målinger viste, at gravide kvinder i EXE havde en bedre søvn og mindre stillesiddende tid end gravide kvinder i CON. De objektive målinger viste dog ingen forskelle mellem grupperne. Der var en klar tendens til mere stillesiddende adfærd og mindre søvn, efterhånden som graviditeten skred frem. Desuden var kvinderne i EXE mere stillesiddende under COVID-19-restriktionerne, da interventionerne blev leveret online.

Den overordnede konklusion er, at det er muligt at øge det fysiske aktivitetsniveau under graviditeten, da aktiviteter ved moderat til høj intensitet var højere i EXE end CON. Den

effekt, som EXE havde på moderat til høj intens fysisk aktivitet målt objektivt ved hjælp af aktivitetsmåleren, afspejlede sig subjektivt i mindre stillesiddende tid og bedre søvn. I løbet af graviditeten fik kvinder i FitMum-studiet mere stillesiddende tid og mindre søvn, hvilket var særlig udtalt mod slutningen af graviditeten, målt objektivt ved hjælp af aktivitetsmåleren. Selv om vi kun observerede en beskeden stigning i det fysiske aktivitetsniveau i FitMum, kan det være nyttigt at øge det fysiske aktivitetsniveau for at reducere den stillesiddende tid og forbedre søvnen under graviditeten. COVID-19 restriktionerne og onlineintervention i EXE øgede træningsdeltagelsen og opretholdt det fysiske aktivitetsniveau ved moderat til høj intensitet, men øgede den stillesiddende tid. Træningsinterventioner tilbudt med blandet fysisk og online fremmøde, der reducerer den stillesiddende tid, kan være en god strategi og bør undersøges mere. Det er kompliceret at måle fysisk aktivitet, stillesiddende tid og søvn under graviditeten, og der findes ikke et optimalt måleinstrument, men en kombination af subjektive og objektive målinger kan give et dækkende billede.

# Abbreviations

| | |
|---|---|
| ACOG | American College of Obstetricians and Gynecologists |
| ANCOVA | analysis of the covariance model |
| CAT | Consumer activity tracker |
| CLMM | Constrained linear mixed model |
| CON | Control (standard care) |
| COVID-19 | Coronavirus disease |
| DLW | Doubly Labelled Water |
| EXE | Structured supervised exercise training |
| FitMum | Fitness for Good Health of Mother and Child (FitMum-RCT) |
| GA | Gestational Age |
| HR | Heart Rate |
| MET | Metabolic Equivalent of Task |
| MOT | Motivational Counselling on physical activity |
| MVPA | Moderate intensity physical activity |
| PA | Physical activity |
| PAEE | Physical Activity Energy Expenditure |
| PPAQ | Pregnancy Physical Activity Questionnaire |
| PPAQ-DK | Danish Pregnancy Physical Activity Questionnaire |
| PSG | Polysomnography |
| PSQI | Pittsburgh Sleep Quality Index |
| RCT | Randomised Controlled Trial |
| SED | Sedentary time |
| TEE | Total Energy Expenditure |

# Introduction and objectives

Physical activity (PA) during pregnancy has several advantages for pregnant women; benefits include decreased risk of excessive weight gain, gestational diabetes, high blood pressure during pregnancy, premature delivery, difficulties during childbirth, and depression after giving birth [1,2]. On the other hand, pregnancy brings substantial physiological and psychological changes that might lower PA [3], increase sedentary time (SED) [3,4], and disturb sleep [5]. Several international health agencies and the World Health Organisation recommend that pregnant women, without health contraindications, be physically active at moderate intensity for at least 150 minutes per week, preferably every day, and reduce their sedentary time (SED) [6,7]. Nevertheless, few pregnant women adhere to the PA recommendations despite the benefits that are widely known and acknowledged [6,8–10]. In addition, pregnant women spend more than half of their day in SED, which is higher than the general population [4]. Also, pregnant women tend to have poor sleep quality and short sleep time [11,12]. Both SED and sleep are impacted negatively as the pregnancy progresses. There are many ways to optimise PA, SED, and sleep behaviours, and one of the suggested approaches is to increase PA levels [13]. However, it is unknown which strategies to increase PA during pregnancy are more effective. Hence, strategies to increase PA, decrease SED and improve sleep quality among pregnant women must be examined. Lastly, various methods are available to measure PA, SED, and sleep during pregnancy, and newer methods, such as the consumer activity tracker (CAT), need to be investigated.

This PhD thesis is based on a randomised controlled trial (RCT), the FitMum study, which investigated how to increase PA levels in healthy inactive pregnant women. In a three-arm RCT, we compared moderate-to-vigorous intensity PA (MVPA) in pregnant women offered standard care (CON), structured supervised exercise training (EXE) or motivational counselling on PA (MOT). We continuously measured MVPA, other measures of PA, SED and sleep with a Garmin Vivosport activity tracker throughout pregnancy. Additionally, we explored SED and sleep measured by questionnaires at various time points during pregnancy.

## Objectives and hypothesis

The main objective of this PhD thesis was to examine the impact of two different PA interventions offered to healthy, inactive pregnant women on MVPA and other PA outcomes as well as on SED and sleep quality and quantity.

We hypothesised that compared to standard care (CON), structured supervised exercise training (EXE) and motivational counselling on PA (MOT) would improve pregnant women's MVPA, with EXE being more effective than MOT. In addition, other PA outcomes, the impact of PA interventions on SED and sleep, were exploratory. The design, procedures, and interventions of the FitMum study were described in **Paper 1.** The validity of the methods used to measure PA and SED in the FitMum study was investigated in **Paper 2.** The impact of the two PA interventions on MVPA and other PA outcomes was evaluated in **Paper 3** and on SED and sleep quality and quantity in **Paper 4.**

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**Table 1: Papers at a glance**

| Paper number and title | Objective | Design/methods | Results and conclusions |
|---|---|---|---|
| Paper 1: Structured supervised exercise training or motivational counselling during pregnancy on PA level and health of mother and offspring: FitMum study protocol | Description of the FitMum RCT procedures, measurements, and outcomes. | Protocol paper | Not applicable |
| Paper 2: Methods to estimate energy expenditure, PA, and SED in pregnant women: a validation study using DLW | To compare the activity tracker with the PPAQ-DK and to evaluate their validity using the DLW as the criteria method. | Validity study based on data from FitMum participants. Activity tracker and PPAQ data were compared at three time points during pregnancy. Activity tracker and PPAQ-DK data were compared to DLW at mid pregnancy. | When compared to DLW, PAEE from the activity tracker Garmin Vivosport was superior to estimates from PPAQ-DK, but the absolute error of both the activity tracker and PPAQ-DK was significant. PAEE and MVPA measured by the activity tracker were lower throughout pregnancy and SED was higher than what was reported using PPAQ-DK. |
| Paper 3: Effects of Structured Supervised Exercise Training or Motivational Counselling on Pregnant Women's Physical Activity Level: FitMum – Randomized Controlled Trial | To determine if EXE is more effective than MOT on increasing MVPA; and if both EXE and MOT are more effective than CON on increasing MVPA. | Single site three-armed RCT. 220 women were included, and 219 were randomly assigned to CON (45), EXE (87), or MOT (87). The primary outcome was MVPA (minutes per week), measured by a wrist-worn activity tracker, from randomisation to GA week 28. The activity tracker | EXE was more effective than CON to increase MVPA, but MOT was not. No group reached the recommended PA level in pregnancy. COVID-19 restrictions did not affect MVPA level but increased exercise participation in EXE. |

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|---|---|---|---|
| | | was used to measure PA throughout the pregnancy, and PPAQ and DLW were used at specific time points. The primary outcome analysis followed the ITT principle with multiple imputations. | |
| Paper 4: Effects of two physical activity interventions on sleep quantity and quality and sedentary time in pregnant women | To explore the effect of the FitMum interventions on sleep and SED. | The secondary analysis of FitMum RCT (n=219) explored the effect of PA interventions on sleep and SED during pregnancy. Sleep and SED were measured by the activity tracker continuously during pregnancy and by the questionnaires at three time points. | EXE had better sleep quality and less SED than CON when measured subjectively. Objectively measured, no differences were observed between groups, but sleep time decreased and SED increased as pregnancy progressed. SED was increased in EXE during COVID-19 restrictions while the intervention shifted online. |

# Background

This section presents the theoretical framework for the thesis in the context of international state-of-the-art research within the subject area. This section includes the impact of physical behaviours (PA, SED, and sleep) on pregnant women's health, physical behaviour recommendations and measurement tools, and the available evidence to increase PA during pregnancy.

## Health impact of physical activity, sedentary time, and sleep during pregnancy

PA and exercise might be used interchangeably, but they have different definitions, and both positively induce health outcomes in diverse populations [14,15]. PA is any body movement driven by skeletal muscle that requires energy expenditure. For instance, a person's everyday occupational, transportation, and household movements are considered PA. Exercise, which must be planned, repetitive, and structured, is a category of PA that enhances or maintains physical fitness [16]. PA and exercise often decrease during pregnancy, and sedentary time increases [17], but regularly engaging in PA positively correlates with favourable prenatal and maternal health outcomes [18]. For example, being physically active during pregnancy lowers the risk of gestational diabetes, hypertension [19], excessive maternal weight gain [20], and prenatal and postnatal anxiety and depression [21]. Also, PA is associated with a reduced risk of preterm delivery [22].

Furthermore, PA might enhance labour and delivery outcomes [23] and improve neonatal and childhood outcomes [24]. Nevertheless, some women may have contraindications to physical activity, such as vaginal bleeding, pre-eclampsia, twin pregnancy, and gestational hypertension [25]. Also, pregnant women should refrain from any PA that increases their risk of falling or abdominal injuries, such as horse riding and kickboxing [1]. Pregnant women, with no contraindications, can safely engage in PA as it does not harm the mother or fetus [23,26–28]. Therefore, moderate-intensity PA is safe for pregnant women and recommended by various health authorities and organisations [6,26].

Pregnant women are more prone to a sedentary lifestyle [4] and poor sleep [12]. SED is any physical behaviour, such as sitting, lying down, watching television, and other screen-based activities, that do not considerably increase energy expenditure above resting (less than 1.5 metabolic equivalents of task (MET)) [29]. Pregnant women are more likely to spend more than half their day as SED than the general population [4]. Several studies have examined the effect of high SED during pregnancy and found negative consequences on pregnant women with an increased

risk of gestational diabetes mellitus, undesirable maternal and infant delivery outcomes, and maternal metabolic abnormalities [4,30]. Furthermore, sleep is negatively affected by physiological and psychological changes induced by pregnancy, such as increased body weight, urination, anxiety, and stress [11]. Sleep disturbances are negatively associated with many prenatal, maternal, and foetal outcomes, such as pre-eclampsia, gestational hypertension, gestational diabetes, caesarean section, preterm birth, large for gestational age, and stillbirth [31]. According to a recent meta-analysis, 45.7% of pregnant women reported poor sleep quality, which worsened as the pregnancy progressed [32]. A recent systematic review including RCTs showed that PA during pregnancy had a beneficial relationship with sleep quality as PA performed one to three days per week at low- and moderate-intensity enhanced sleep outcomes. In addition, incidental PA, such as housework, leisure, commute activities, and structured exercise training, is beneficial to sleep during pregnancy [33,34].

With all the well-established and well-known benefits of PA, the balance of SED, and good sleep during pregnancy, many health agencies frequently publish, release, and continuously update recommendations for pregnant women. The next section presents a brief example of past and current PA recommendations and available SED and sleep guidelines during pregnancy.

## Recommendations for physical activity, sedentary time, and sleep for pregnant women

Historically, the physical behaviours recommendations during pregnancy were mainly focused on PA, which can be traced back to 1959 when the United State Children's Bureau issued a general recommendation for prenatal PA. The recommendation encouraged pregnant women to do housework, gardening, walk, and swim but not participate in sports. It was not until 1985 that the American College of Obstetricians and Gynecologists (ACOG) considered aerobic PA safe during pregnancy. However, there were some cautions, such as no running and no more than 15 minutes of PA that dramatically increased the heart rate [3]. Many milestone studies have emerged following the 1985 ACOG recommendation that massively contributed to the ACOG 1994 and 2002 guidelines [3,35]. These studies contributed to the recommendations of 30 minutes of moderate intensity during most, if not all, days of the week during pregnancy when there are no contraindications to PA. Similarly, and simultaneously, there was international recognition and implementation of PA guidelines during pregnancy. For instance, Canada, the United Kingdom, and the Netherlands recommended 30 minutes/day or 150 minutes /week of moderate intensity [3],

which were aligned with the World Health Organization 2020 guidelines on PA and sedentary behaviour recommendations for pregnant women [7]. Currently, the Danish Health Authority recommends that healthy pregnant women be physically active at moderate intensity for at least 30 minutes daily. The Danish Health Authority encourage PAs such as walking and hiking, swimming, running, muscle-strengthening exercises, cycling, spinning, and aerobics but discourage contact sports and team sports, such as skiing or riding, and vigorous-intensity physical activities [36]. Recently attention has been paid to vigorous-intensity PA during pregnancy. Evidence is emerging that pregnant women who are used to exercise at vigorous intensity can continue to do so; hence several newly released guidelines advise MVPA [6,37–39].

There are few guidelines regarding SED during pregnancy due to inconsistent findings in the literature about SED, the benefit of maternal health, and the vast disparity between sedentary behaviour classifications and measurement techniques [4]. The World Health Organization 2020 guidelines on PA and sedentary behaviour advises pregnant women to interrupt SED periods with any level of PA (including light intensity) that positively affects health. This recommendation relied on evidence generated from nonpregnant populations [7]. The Australian guidelines for PA in pregnancy and postpartum recommend that pregnant women limit their time spent lying down and sitting, as SED can counteract the advantages of PA [40]. Noticeably, the World Health Organization and the Australian recommendations for SED during pregnancy did not specify the maximum time spent as SED [40,41].

There are no sleep guidelines during pregnancy as recommendations are similar to those for the general adult population, which is 7 to 9 hours each day, mainly at night [42–44]. Although sleep is well acknowledged as a short and distributed behaviour during pregnancy, and pregnant women are generally poorer sleepers than non-pregnant women, sleep in pregnancy is rarely discussed by healthcare providers or addressed in research on health outcomes [42,43]. The Canadian 24-hour movement guidelines for adults aged 18-64 years are recommended to have a regular sleep schedule of 7 to 9 hours, with regular bedtimes and wake-up times [45]. The ACOG has not mentioned sleep or SED in the current (2020) committee opinion about PA and exercise during pregnancy [1]. Lastly, PA, SED, and sleep have been investigated separately [46–48], and no guidance has been established during pregnancy [34]. Therefore, the effect of PA on SED and sleep needs more exploration [33,34]. Although the recommendations and interventions primarily increase PA in pregnant women, there is a trend toward the 24-hour movement balance, decreasing SED, investigating the recommended amount of SED during pregnancy [49] and recognising and improving prenatal sleep health [31].

### *The 24-hour movement behaviour during pregnancy*

The 24-hour movement recommendations for children and adults were recently made a priority by many countries, such as Canada [45], Australia [50], South Africa [51] and Saudi Arabia [52], because mounting evidence shows how PA, SED, and sleep collectively affect the general health [46,47]. According to a recent study, cardiometabolic biomarkers and all-cause mortality were linked to the composition of 24-hour movement behaviours. A systemic review of observational studies using compositional data analysis explored the relationships between health outcomes for adults and sleep, SED, and PA. For instance, they found that switching from SED to MVPA positively impacted all-cause mortality [46]. The Canadian 24-hour movement guidelines recommended a new strategy for adults, which balances PA, SED, and sleep during the day [45]. The World Health Organization guidelines on PA and SED [7] and the Canadian 24-hour movement guidelines [45] introduced a new approach that recommends a balanced physical behaviour during the day. Yet, the application of compositional data analysis during pregnancy is limited [53]. A few studies investigated how 24-hour movement profiles vary throughout pregnancy and how it may affect women's health [53,54].

Even with all the well-known and recognised advantages of PA during pregnancy, few pregnant women meet the PA recommendations [8–10]. Also, many barriers limit pregnant women from being physically active [55,56]. Therefore, in the next section, there is a background presented about the prevalence of physical inactivity, SED, and sleep and some of the limitations that prevent pregnant women from achieving the PA recommendations.

### *Adherence to the recommendations*

The prevalence of noncompliance with PA guidelines is high among pregnant women worldwide, ranging from 28% to 60% [8–10,25,57]. In Denmark, approximately 60% did not reach the health authority recommendations for PA [9,36]. Consequently, SED is too high, and even though some pregnant women adhere to the PA guidelines, they still spend excessive time as SED [57,58].

There are many reasons for not achieving the recommendations, which can vary between culture, education level, and region. Generally, three categories of barriers might limit pregnant women from being physically active, i.e., intrapersonal, interpersonal, and environmental [55,56]. For instance, intrapersonal barriers include fatigue, lack of time, pregnancy discomforts, or safety concerns about the suitable types of PA [56]. Lack of knowledge, work obligations, and social support from family or friends are the foremost interpersonal barriers [55,56,59]. Finally, environmental barriers include but are not limited to the accessibility and affordability of exercise

facilities [56]. Also, clinicians limited knowledge about the PA recommendations for pregnant women [60,61], and the beliefs, motivations, and perceptions about PA among pregnant women are all possible barriers [62–65]. Also, unclear recommendations or the lack of a personalised tone in the recommendations might discourage pregnant women from being physically active [66].

Therefore, frequently measuring PA at the population level using reliable tools to identify trends in adherence to PA recommendations is needed. These tools should be capable of determining PA frequency, duration, and intensity. Hence, the next section presents the current and emerging methods used to measure PA, SED, and sleep among pregnant populations. The method section will include a detailed discussion of measurement methods used in this thesis and a comparison with other methods.

## Measurement tools for physical activity, sedentary time, and sleep in pregnant women

There are a variety of ways to measure PA, SED and sleep. These measurement tools fall under subjective and objective methods. Subjective methods rely on the individual to either keep track of events as they happen (i.e., diaries or logs) or to remember events from the past (i.e., questionnaires) [67]. During the past 50 years, the self-reporting subjective method has been the most utilised method to measure PA [68,69]. The measurement of PA by self-reporting tools during pregnancy, mainly questionnaires, has contributed significantly to studying PA's impact on general health, PA surveillance, and assessing compliance with PA guidelines [68,70]. Many questionnaires, such as the Pregnancy PA Questionnaire (PPAQ), are available to measure PA among pregnant women. PPAQ is specifically designed to determine prenatal PA and SED in the current trimester [71], and it is a commonly used and recommended tool [72,73]. Questionnaires, in general, are inexpensive, induce a low burden on the participant and the researcher, and can assess different domains of PA [3,67]. Nevertheless, PPAQ, like other questionnaires, has its pitfalls, such as overestimation of PA [74,75], underestimation of SED [76], and low construct validity, especially when compared to the objective method [72]. Moreover, questionnaires like PPAQ might be unable to detect incidental PA [67]. Lastly, PPAQ is not designed to measure sleep, as sleep considers different metrics [71]. One of the well-known sleep questionnaires is the Pittsburgh Sleep Quality Index (PSQI) which assesses sleep quality and disturbance over a month [77] and has been validated among pregnant women [78]. The PSQI subjectively measures sleep quality, quantity, and disturbance [77,79].

Objective methods determine one or more biological or movement reactions, such as heart rate (HR), acceleration, or energy expenditure [67]. The DLW is considered the “gold

standard" for measuring total energy expenditure during free-living, and it is safe and can be applied during pregnancy [80–83]. As PA requires energy expenditure, physical activity energy expenditure (PAEE) can be computed from the DLW when measures of resting energy expenditure and the thermic effect of food are known or estimated. Compared to direct calorimetry, where the subject must stay at least 24 hours in the lab [84], DLW is applied in free-living conditions, which might put a little burden on the participants [67]. However, DLW is expensive and requires technical expertise to analyse and interpret the results.

The most common objective measure of PA in research is by an accelerometer-based device [85–87]. When these devices were first introduced in the 1980s, accelerometer-based devices were viewed as an innovative but specialised technique due to several drawbacks, e.g., high device costs, dependability, calibration, and validity issues. Since 2004, the technical developments of accelerometers, which can be worn on the hip, wrist, or thigh, have been remarkable [87,88]. An accelerometer measures the acceleration of the body over time and then estimates the time and intensity of PA [85–87]. Most accelerometers measure acceleration in three axes and the data are available to researchers via specific software to compute and estimate PA, SED, or sleep [87] . Compared to a few years ago, it is now possible to construct a wearable accelerometer-based PA monitor with significantly larger memory and battery capacities, a more comprehensive acceleration range, a smaller size, and less expense. At the same time, researchers have begun to utilise the raw acceleration signal data directly rather than the manufacturer-specific algorithms [88]. Accelerometers provide many positive features, such as comprehensive measurements of physical behaviours. The accelerometer can estimate SED, sleep, and PA intensity, frequency, and duration; it can retain data for weeks at a time, and it is easy to use and reasonably priced [67,88]. Moreover, it is recommended that objective measures of PA during pregnancy (i.e., accelerometer) should be utilised as the minimum assessment standard because they can tackle several issues with self-report estimations [89]. Accelerometers, especially wrist-worn, are practical and desirable in terms of comfort and compliance when measuring PA during pregnancy [90]. However, the accelerometer cannot capture activity types such as cycling, swimming, or using stairs; and the hip accelerometer overlooks upper-body exercise. Also, data reduction, transformation, and processing require time and expertise [67,88]. Most importantly, well-defined cut points that recognise different activity patterns and time spent in each PA intensity are unavailable for pregnant women, which are necessary to compute PA intensity and PAEE [90]. Although the "gold standard" to measure sleep is polysomnography (PSG) [91,92], accelerometers can estimate sleep time [92].

Heart rate (HR) monitors, placed on the wrist or chest, are considered one of the objective methods to capture PA. There is a physiological relationship between HR and PA as HR

increases when PA intensity increases. In addition, HR monitors can estimate energy expenditure based on assuming a linear relationship between HR and oxygen consumption [67]. HR monitors are considered relatively inexpensive and highly correlated with MVPA, but during low-intensity PA, HR monitors placed on the wrist might have difficulties detecting PA. HR monitors might also detect stimuli, such as emotions, medication, and caffeine, falsified as PA [67,93].

Another objective method for measuring PA, which is not a research-only device as is the case with accelerometers, is a consumer activity tracker (CAT). CATs, including pedometers, activity-tracking smartwatches, and fitness trackers, offer instant feedback to the use and have recently been utilised in health studies [94]. For example, Fitbit, Garmin, and Samsung Gear Fit are all available CATs allowing users to track their PA and sleep [95,96]. A CAT, worn on the wrist with an embedded HR monitor, is an emerging technology designed for consumers and individuals and is not explicitly meant for research purposes. However, a large body of research utilises CATs to investigate, intervene and monitor physical behaviours [94]. CATs can, via accelerometers and physiological sensors (e.g., HR) [96–98], capture many physical metrics such as total PA, steps, MVPA, floors climbed, PA type, SED, HR, energy expenditure, stress, and sleep and can save data for weeks [99–101]. Some intervention studies have shown that CATs can influence participants to increase PA levels, which improves health outcomes [99–101]. Studies among pregnant women showed that CATs are acceptable for longtime continuous monitoring, measuring PA and sleep, and real-time feedback [102,103]. Using a CAT with a digital platform that stored and analysed the data remotely and then sent the results to medical professionals was feasible among pregnant women for almost the entire pregnancy period [104]. Continuous monitoring offers real-time information that the obstetrician and the midwife may use in antenatal counselling to tailor specific health recommendations [104,105].

Several limitations are associated with CATs, such as proprietary algorithms and unclear information about software updates [106,107]. While previous research studies have demonstrated relatively good accuracy of CAT in estimating total energy expenditure (TEE) [108] and measuring MVPA [109], there is a need for more rigorous and standardised validation of these devices in free-living settings [97,110]. Lastly, no previous studies have validated the performance of CATs in pregnant women [72], including PA intensity, energy expenditure, and sleep [110].

Presumably, there is no perfect method to measure physical behaviour. Each method has advantages and disadvantages. The most optimal method is determined by many factors, such as the study's objective and the setup [111]. However, the recommendations are to use a combination of tools to complement each other, detect different physical behaviours [112,113], and rely more on objective measurements during pregnancy [89].

## The available evidence for increasing physical activity during pregnancy

RCTs are considered a reliable source of evidence [114,115]; many PA guidelines and strategies during pregnancy have been developed and implemented based on evidence generated from RCTs [3,40,116]. The most-used PA intervention was supervised structured exercise training [20,117–119]. However, emerging evidence suggests alternatives to increase PA during pregnancy, such as interventions based on behaviour theories, including motivation, person-centred strategy, goal setting, and feedback [120,121]. Most studies on PA during pregnancy focus on people that are overweight or obese [122–127]. Fewer studies [117,128,129] have studied healthy, normal-weight pregnant women; none have primarily investigated the impact of offering PA interventions on pregnant women's actual PA levels [110,130]. Although the benefits of PA for pregnant women's health are well-known, more rigorous RCTs involving multicomponent PA interventions to test the effectiveness of interventions during pregnancy are needed [4,33,34,41,121,130]. Also, few studies investigated the best strategies to implement PA during pregnancy, such as combined supervised structured exercise training and motivational counselling on PA in RCT settings [121,131]. Furthermore, most RCTs and recommendations rely on questionnaires to assess PA. Hence, there is a need to include an objective method or to combine self-report and objective tools for a better assessment of PA [89,121]. Moreover, a novel method is needed to help pregnant women to be aware of, understand, and reflect on their physical behaviours and PA [89,110,132]. Lastly, there is an urgent need to explore the effect of PA interventions on SED and sleep during pregnancy [4,33,34].

# Methodological considerations

This section presents the thesis's methods and materials and describes the FitMum study protocol, procedures, interventions, and measurement tools used. The validity and comparison of the measurement tools used in the FitMum study to measure PA, SED, and sleep will be described and discussed in this section.

## Study design for the FitMum randomised controlled trial

### *Ethics and setting*

All papers included in this thesis are part of the FitMum study, which was approved by the Danish National Committee on Health Research Ethics (#H-18011067) and the Danish Data Protection Agency (#P-2019-512). The study was registered at clinicaltrials.gov (NCT03679130) and adhered to the principles of the Helsinki declaration. Before the participants were included in the study, written informed consent was obtained. The FitMum study was conducted from October 2018 to May 2021 at the Department of Gynaecology and Obstetrics at Nordsjaellands Hospital in Hillerod, Denmark's capital region. Nordsjaellands Hospital is a public hospital; therefore, prenatal care was free and participation in the FitMum study was voluntary.

### *Inclusion and exclusion criteria*

Inclusion criteria involved obtaining written informed consent, being 18 years or older, having a maximum gestational age (GA) of 15 weeks, having an ultrasonic-confirmed viable intrauterine pregnancy, having a body mass index of 18.5–45 kg/m$^2$, and weighing maximally 150 kilograms (kg) (pre-pregnancy weight or first measured weight in pregnancy). In addition, the participant had to be able to wear a Garmin Vivosport [133] activity tracker 24/7 until one year postpartum and to have a smartphone. Women were excluded if they had engaged in structured exercise at MVPA for more than one hour per week during early pregnancy, had a previous preterm delivery, had obstetric or medical complications, used a medically prescribed drug, had multiple pregnancies, abused alcohol or spoke no Danish.

### *Rationale and design*

The design and description of the FitMum study were inspired by the Template for Intervention Description and Replication (TIDieR) [134]. Moreover, prenatal and maternal health stakeholders (e.g., midwives and pregnant women) participated in discussions and knowledge

exchanges during the study development. Twenty-seven semi-structured interviews with Danish pregnant women, midwives, and obstetricians explored motivational factors and barriers to PA participation during pregnancy. Participants were not actively involved in the study's recruitment and execution but were part of a process evaluation of the FitMum study [135]. We designed a three-arm RCT as it was needed to conduct an adequately powered trial that explored the effect of PA interventions on maternal health and the "best" way to increase actual PA in pregnant women [41,110]. Also, we wanted to test the effect of PA interventions across all trimesters on maternal PA, health outcomes, SED, and sleep and the long-term effect of the interventions during the postpartum period [34,41,110].

The supervised exercise training and motivational counselling on PA represent two distinct strategies for establishing and sustaining an active lifestyle. Consequently, we found it worthwhile to explore and generate evidence on how supervised exercise training and motivational counselling on PA can be applied during pregnancy [34,130]. We chose MVPA as the primary outcome for many reasons. The current PA recommendation for pregnant women is moderate intensity PA [3,7,26,36,40], and PA at moderate intensity is highly associated with health outcomes [19,21,24,136]. However, vigorous-intensity PA during pregnancy has recently been explored, as there is evidence that pregnant women who regularly engage in vigorous-intensity exercise can continue; therefore, numerous recently released guidelines recommend MVPA [6,37–39]. Furthermore, studies that merely evaluate MVPA levels during pregnancy were limited [137]; hence, we wanted to capture PA at moderate intensity and beyond. Also, in the FitMum study, we measured many maternal and neonatal outcomes, such as sleep and epigenetics, as we wanted to investigate the impact of MVPA on these outcomes. We planned to make the financial costs of the two exercise programs equal so that women participating in the two interventions incurred the same costs and staff time.

The FitMum participants had four visits during the study: visit 1 for baseline measurements (before GA week 15 and before the randomisation, which was no later than GA week 16), visit 2 (V2: GA week 28), visit 3 (V3: GA week 34), and delivery (approximately GA week 40). Data collection and procedures are presented in **Table 1, Paper 1 and Figure 2, Paper 3**.

### *Groups and interventions*

The standard of care during pregnancy, delivery and the postnatal period provided to all women giving birth at Nordsjaellands hospital was equally available to all three FitMum study groups. This standard of care entails three visits with their primary care physician (GA weeks

6–10, 25, and 32), five to six consultations with a midwife (GA weeks 14–17, 29, 36, 38, 40, and if still pregnant, around week 41 as well), and two ultrasounds at GA weeks 12 and 20. The CON group received no PA intervention but wore the activity tracker for measurement purposes. The activity tracker has a watch-like face that displays the time and battery level. For the two intervention groups (EXE and MOT), the targeted PA level for these participants were at least 30 minutes per day at a moderate intensity, as recommended for healthy pregnant women in Denmark [36]. None of the groups received instructions or recommendations about SED or sleep.

Exercise training in EXE was applied in groups under the supervision of research members of the FitMum research team (exercise physiologists, physiotherapists, and public health scientists). The EXE participants could choose between sessions on all weekdays, which took place in the early mornings or late afternoons, and a session on Saturdays that began before noon. Participants were offered to participate in three sessions per week of one-hour workouts at moderate intensity, with one workout in a public pool and two in a gym. In the swimming pool session, participants spent 15 minutes swimming and 45 minutes exercising in the water using plates, balls, dumbbells, or their body weight. In contrast, the gym sessions included 30 minutes of stationary bike training (which combined hill climbing and high cadence intervals) and 30 minutes of another exercise, such as using elastic bands, exercise balls, mats, weights, or body weight. The researchers guided EXE participants to reach the HR "zone" for moderate intensity, which is at a HR less than 60-80% of the age-predicted maximal HR [25] or that is rated as 12–14 on the Borg scale for perceived exertion [138]. Also, the activity racker's HR monitor was utilised to help EXE participants understand the target HR "zone" in the first session only. Thus, the EXE participant was guided and monitored throughout the sessions to reach moderate intensity PA level, but most importantly, to listen to their body, pay attention to their body signals, and adjust accordingly [27].

The MOT group received weekly SMS reminders and was offered four individual counselling sessions and three group counselling sessions on PA. The MOT sessions were also led by research members of the FitMum research team (exercise physiologists, physiotherapists, and public health scientists). The MOT group utilised the activity tracker beyond the measurement aim as in EXE and CON. The activity trackers were used as an intervention component to encourage the participants to raise their PA levels [100,101,139–141]. Also, tailored weekly SMS reminders encouraged them to reach moderate intensity levels. During the individual sessions, participants' challenges, desires, knowledge, prior experiences, and plans about PA were discussed to determine their unique motivations for leading physically active lifestyles. To help participants understand their PA level, feedback on previous PA performances was given during individual sessions based

on activity data collected from the activity tracker. Group meeting sessions focused on discussing issues related to PA during pregnancy, and the research members of the FitMum team were facilitators while the participants chose the topics of dialogue. **Figure 1** visually presents the content of the two intervention groups.

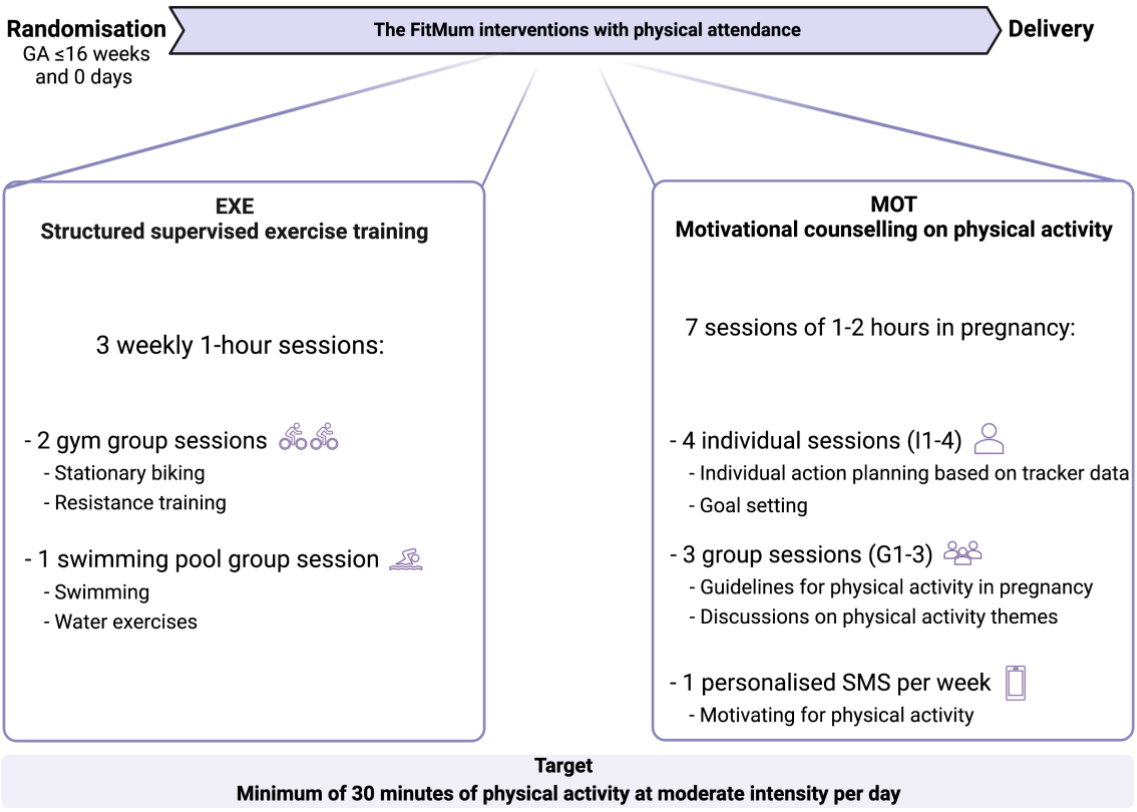


**Figure 1: Components of the FitMum interventions.**

### *Sample size and randomisation*

The FitMum study was powered to detect an overall significant difference in the primary outcome, MVPA, between the three groups and a significant difference between the two intervention groups (EXE vs. MOT) from randomisation to visit 2 (GA week 28). For the power calculation, based on the Danish health authority recommendations of 30 minutes a day of MVPA for pregnant women, or (30 minutes*7 days= 210 minutes a week) [36], we estimated an average weekly MVPA of 210 minutes for EXE, 150 minutes for MOT, and 60 minutes for CON, and the standard deviation was based on a previous study [142]. Consequently, 220 women were planned to include and to randomise, with 44 in the CON group and 88 in each intervention group in a 1:2:2 ratio **Figure 1, Paper 1**. In addition, when calculating the sample size, we predicted a 20% loss to follow-up rate, as found in comparable PA studies in pregnant women [143–146]. The flowchart for

the FitMum enrolment, randomisation, and allocation is presented in **Figure 1, Paper 1.** The data analysis, completers, and intention to treat are presented in **Figure 1, Paper 3**. The investigations of PA on SED and the sleep quality and quantity (**Paper 4**) were exploratory and secondary analyses of the FitMum study. Therefore, no calculation of sample size or power was made.

## Methods to measure physical activity, sedentary time, and sleep during pregnancy

In **Paper 1**, the FitMum design's details are discussed, and briefly, the methods used to measure PA, SED, and sleep. **Paper 2** detailed the measurement tools used in the studies included in this thesis and presented the validity and comparison of the methods used to measure PA and SED in the FitMum study. A sub-section in **Paper 4** compared the PSQI and the activity tracker.

### *Activity tracker selection and outcomes*

Besides using the most common questionnaire among pregnant women to measure PA [72,73] and the "gold standard" to measure energy expenditure [80–83], we wanted to include a new technology component, "digital health", in the FitMum study that was commercially available and objectively assessed PA levels, SED, and sleep. Furthermore, as few published studies utilised these devices among pregnant women [110], we wanted to know how an influential giving tool that directly measures and shows the PA level to the participants can motivate pregnant women to move. Therefore, before the FitMum study started, three CATs, i.e., Fitbit Charge 2, Polar 370, and Garmin Vivosport, were tried out by a few of the FitMum investigators to choose from among them. We were looking for a CAT that was convenient to wear, had both an HR sensor and an accelerometer, and could be integrated with an application programming interface platform specifically designed for research purposes. The research team selected Garmin Vivosport for two main reasons:

1- The Garmin Vivosport's capability to connect with a third-party research platform, which was not feasible for Polar, and
2- The Garmin Vivosport wrist strap was much more convenient than the Fitbit.

Moreover, the Garmin Vivosport is water resistant and can be worn while showering and during water activities such as swimming. All participants were given a Garmin Vivosport activity tracker (Garmin International) with a built-in HR monitor and accelerometer [133]. It had to be worn on the non-dominant wrist 24/7 from inclusion until one year after giving birth. The activity tracker is lightweight (25.5 grams), has a battery life of up to seven days, and keeps the activity and HR data

for 14 days [133]. **Figure 2** shows the Garmin Vivosport activity tracker we used in the FitMum study.


**Figure 2: Garmin Vivosport worn on my wrist.**

**The back of the tracer shows the photoplethysmography shining a green light.**

On the first visit (visit 1), the participant was instructed verbally and provided with a printed handout on synchronising and charging the activity tracker regularly. Also, participants were encouraged to write to us if they faced any difficulty or technical issues with the activity tracker. At visit 1, a research team member assisted the participant in installing the Garmin app on her phone and connected the activity tracker to the Garmin Connect app via Bluetooth [147]. The research team member entered the participant's weight, height, birthday (for age), and sex and set the activity tracker screen to show only the clock and battery life. We did not want the participant to be motivated by the activity tracker during the baseline period. Although, after randomisation, the activity trackers were utilised as an intervention component in MOT to raise their PA, so the interaction between the activity tracker and the participant in the EXE and CON groups was inevitable. Part of the first MOT session was about the activity tracker features and abilities. For instance, participants' questions about the activity tracker were answered during the session, the watch face changed to match their desire, and steps and intensity goals were set accordingly.

Additionally, all participants could access their activity tracker data via the Garmin Connect app to visually track their activities or change the features and goal settings [147] (**Figure 3)**.


**Figure 3: My activity data is shown on Garmin Connect. Preferences and statistics of activities on a weekly, monthly, and annual basis are set and shown here.**

The data from the activity tracker was transferred every time the participant opened the Garmin app and turned on the phone's Bluetooth or just turned the Bluetooth on, and synchronisation was monitored through a research platform (Fitabase, San Diego, US). Participants were asked to sync every day. An email reminder would be sent if a participant had not synced for more than seven days. If there was no syncing after the reminder, we called/texted the participant to check if an issue had occured.

The FitMum study group does not have access to Garmin's proprietary algorithms. Still, as other researchers use similar CATs, we assume that the demographic data entered in the Garmin app influences the PA variables derived from the activity tracker [96,148]. Garmin's algorithms calculate steps, moderate intensity, vigorous intensity, active calories, and active time. However, we derive and calculate some variables from the activity tracker data. For instance, we calculated TEE by adding PAEE, basal, and thermic effect of food, which was assumed to be 10% of TEE [149,150]. **Table 1** shows a complete overview of the data provided by the activity tracker (Garmin Vivosport) via the Fitabase platform.

**Table 2: Data from the activity tracker**

| Data from the activity tracker | Description (unit) |
|---|---|
| Active Kilocalories | Active kilocalories burned through actual movement (Kcal/day) |
| Steps | Count of steps (steps/day) |
| Active Time | When the activity tracker detects that the wearer is considered active (min/day) |
| Moderate Intensity | Cumulative duration of activities of moderate intensity, lasting at least 600 seconds at a time. Moderate intensity is defined as activity with MET value range 3 - 6 (min/day) |
| Vigorous Intensity | Cumulative duration of activities of vigorous intensity, lasting at least 600 seconds at a time. Vigorous intensity is defined as activity with MET value > 6 (min/day) |
| Minimum Heart Rate | Minimum of heart rate values captured in beats (beats/min) per day |
| Max Heart Rate | Maximum of heart rate values captured in beats (beats/min) per day |
| Average Heart Rate | Average of heart rate values captured in beats (beats/min) per day |
| Resting Heart Rate | Averaged resting heart rate values captured in beats (beats/min) per day |
| Floors Climbed | Number of floors climbed (floors/day) |
| MVPA | Sum of minutes of moderate and vigorous intensity (min/day) |
| Awake sedentary time* | Little to no activity. Monitored from the 15 minutes Epoch. This could be due to minimal movement, sitting, resting, but not sleeping (hr/day) |
| Sleep time * | Sleep time excluding time in bed not sleeping (hr/day) |

* Indirectly calculated from the activity tracker.

The activity tracker categorised activity based on intensity for an epoch of 15 minutes (Epoch log). For instance, if the user spent five minutes sitting still, five minutes walking, and then five minutes running, the duration value would be 15 minutes for all three recordings, but the time would be 5 minutes for each. The activity tracker then categorises time into sedentary (including sleeping time), active, or highly active. From the Epoch log, we got the total sedentary time.

The activity tracker reports sleep time spent in each sleep stage: light, deep, rapid eye movement, and awake time during sleep. This dataset has a row for each night for each

participant when the participant had the tracker on during the whole sleeping time. We calculated sleep time by adding all sleep stages (light + deep + rapid eye movement) except the awake time during sleep. We calculated SED by subtracting sleep time from total sedentary time. The tracker does not measure naps during the daytime [133], which might be prevalent during pregnancy [151].

Throughout the FitMum study period (from October 2018 to May 2021), the Garmin Vivosport software was routinely updated, which is unavoidable, and sometimes this update was necessary [106,107]. For instance, a few participants who wanted to join the FitMum study on the first visit and had a Huawei smartphone could not connect the Garmin Vivosport to their phones. Garmin found a technical issue that prevented the Huawei smartphone from connecting to the Garmin Connect App; hence the activity tracker needed an update of the software to overcome this issue [152]. Since it was first released in approximately mid-2017, and as of December 2019 (the last time Garmin Vivosport software was updated), the Garmin Vivosport was updated 17 times [153]. Most software updates were due to fixing and improving features and functionality, such as battery life, syncing, and weather communications. However, some updates were related to algorithms improvements. For example, a few updates were for improving the sleep algorithms, resting HR calculation, and intensity minutes algorithms. Since the recruitment of the FitMum participants was not at the same time, participants recruited later in the study had newer and improved algorithms. Hence, the updates may affect how the activity tracker's PA and SED were evaluated in the validation study (**Paper 2**) and when we tested the effectiveness of FitMum interventions (**Papers 3 and 4)**.

***Pregnancy Physical Activity Questionnaire***

The Pregnancy PA Questionnaire (PPAQ) was developed and designed to measure PA during pregnancy [71]. In the PPAQ, there are questions on the amount of time spent engaging in sedentary activities (n=5), light-intensity activities (n=8), moderate-intensity activities (n=15), and vigorous-intensity activities (n=2), as well as two open questions asking participants to list activities that were not listed. Additionally, some responses corresponded to PA categories: inactivity (n=3), household activity (n=11), occupational activity (n=5), sport/exercise activity (n=7+2 open-ended), transportation activity (n=4), and sport/exercise activity (n=7+2). Before conducting the FitMum-RCT, PPAQ was translated into Danish and validated in a Danish pregnant population (PPAQ-DK) [154]. During the FitMum study (before GA week 15, GA week 28 and GA 34), the participants answered PPAQ-DK digitally. The questionnaire took approximately less than 20 minutes to answer. When PPAQ was published in 2004 by Chasan-Taber et al. [71], it was validated using accelerometer algorithms worn on the hip during fixed-duration simulated

laboratory activities. These algorithms have been demonstrated to function poorly in free-living contexts, notably in detecting sedentary and light-intensity activity [155]. Moreover, PPAQ has two questions that measure SED, and the definition of sedentary behaviours has changed; therefore, we adopted the 2017 consensus definition of sedentary behaviours [156]. Moreover, we were inspired by Gibbs et al. [76] and the Diet, Anthropometry, and PA (DAPA) Measurement Toolkit for PPAQ [157] and included three questions, which were considered as light PA, and now it is SED (five questions in total instead of two). The scoring of PPAQ-DK was executed in an excel file according to instructions by the research group that developed the PPAQ [71]. Each answer of the PPAQ-DK corresponds to a duration (time spent in an activity) * intensity; this intensity (in MET) is adapted from the activity compendium [158], which is not pregnancy-specific [159]. Body composition may impact MET values during pregnancy; therefore, changes in the MET system for pregnant women are needed [160].

***Doubly Labelled Water***

DLW considers the "gold standard" technique for objectively measuring free-living TEE and is safe, even for pregnant women, as it relies on stable, non-radioactive isotopes [80–83]. The DLW technique is based on the principle that the disappearance rate of the heavier stable isotope of hydrogen ($^{2}H$) reflects the water turnover rate, and the disappearance rate of the heavier stable isotope oxygen ($^{18}O$) reflects both water and $CO_2$ turnover rates. Therefore, with time, the difference between the disappearance rates of $^{2}H$ and $^{18}O$ represents the rate of $CO_2$ production. From $CO_2$ production, we computed TEE [161]. Before we calculated TEE, we checked the quality of the DLW result on the log scale and plotted the linear line of the residuals of disappearance rates of $^{2}H$ and $^{18}O$ over time (days [1, 4, 7, 11 and 14]). **Figure 4** shows an example of the quality check of DLW data.

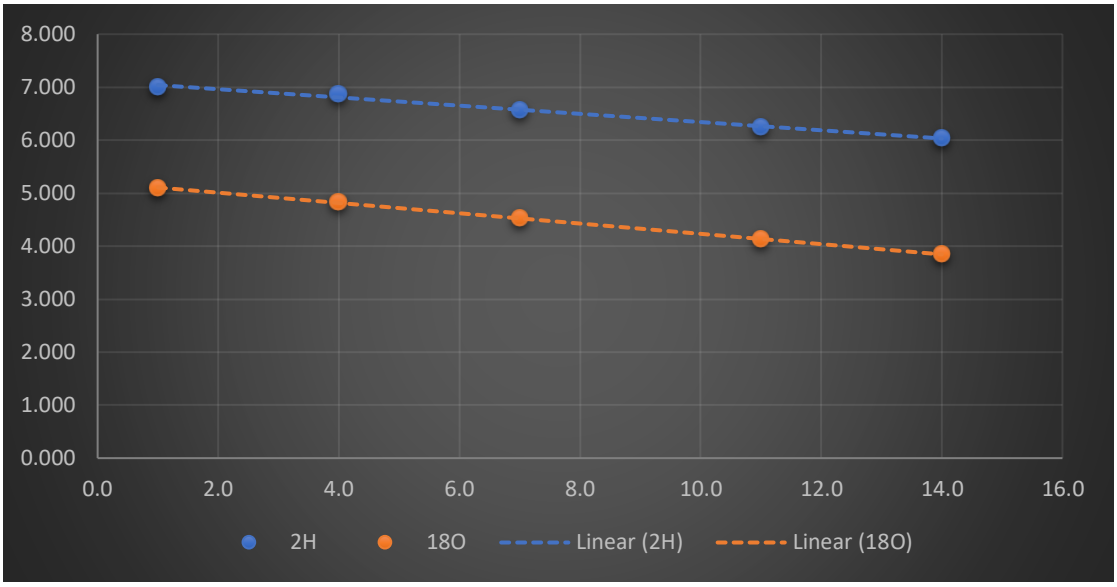


**Figure 4: Quality check of DLW data for one participant. Days on the DLW test in the x-axis and the logarithmic of the enrichment rate of $^{2}H$ and $^{18}O$ in the y-axis.**

Based on the energy equivalent of $CO_2$, the rate of $CO_2$ production can be converted to TEE [161]. Finally, the TEE was calculated using the modified Wier equation [162,163]:

$$22.4\left(3.9\left(\frac{rCO2}{FQ}\right)+\ 1.1\ (rCO2)\right)\times\frac{4.184}{1000}$$

The Food Quotient (FQ) is assumed to be 0.85 [162,163]. Basal metabolic rate was estimated by an equation for pregnant women [149]. Subsequently, PAEE was determined by subtraction of basal metabolic rate and the thermic effect of food (assumed to be 10% of TEE) from TEE [149,150]. PA level was calculated by dividing TEE by basal metabolic rate [162]. However, PA level varies both between and within individuals as basal metabolic rate rises, and PA will represent a comparatively smaller portion of TEE [164,165].

### *Pittsburgh Sleep Quality Index*

The Pittsburgh Sleep Quality Index (PSQI) was introduced in 1989 as a measurement tool to assess sleep quality and disturbance over a month [77]. The PSQI has 19 questions that fall into seven components measuring 1) subjective sleep quality, 2) sleep latency, 3) sleep duration, 4) sleep efficiency, 5) sleep disturbance, 6) use of sleep medication, and 7) daytime dysfunction. The first four questions ask about specific times of routine sleep habits 1) what time typically go to sleep at night, 2) how long it typically takes to fall asleep each night, 3) what time typically wake up throughout the past and 4) how many hours of genuine sleep received each night over the past month. The questions are each equally weighted on an 0-3 scale, and it measures sleep quality and disturbances. Finally, the seven component scores are added to get the overall PSQI score,

ranging from 0 to 21; lower numbers imply better sleep quality [77,79]. Sleep quantity and quality were assessed during the FitMum study by the Danish version of the PSQI. PSQI has been validated and used among pregnant women [78] and has been used to measure the effect of PA interventions on sleep quantity and quality [33,166]. Like PPAQ-DK, PSQI was sent to the FitMum participants and self-answered digitally before GA week 15, GA week 28 and GA week 34.

## Validity and comparison of physical activity, sedentary time, and sleep measurements during pregnancy

### *Comparison of the activity tracker, the Pregnancy Physical Activity Questionnaire and the Doubly Labelled Water*

PPAQ-DK determines PA in the current trimester, whereas the activity tracker continuously measures PA and SED. Consequently, when comparing the tracker with PPAQ-DK, we averaged the tracker data for the baseline period, from randomisation to GA week 28 and from GA week 28 to GA week 34. The DLW was only utilised at GA week 28 (**Figure 1, Paper 2)**.

Questionnaires such as PPAQ are cheap, easy to administer, and can rank PA [167]. However, as there is progress in the device measurement of PA, questionnaires need to adapt quickly to these changes and progress. Also, there is a trend that PA guidelines are based on device measurement of PA; PPAQ, like other questionnaires, needs comprehensive validation and updated efforts to capture PA and SED accurately [4,112,113,168]. In addition, there are no prior studies comparing the tracker, PPAQ, and the DLW during pregnancy. Notably, no study investigated the validity and reliability of the Garmin activity tracker before the FitMum study started. A systematic review including 12 Garmin activity trackers was conducted in 2020, though not the Vivosport, and investigated the validity of steps, MVPA, EE, HR, and sleep in adults [169]. In 2021, a study investigated the validity of three CATs, including the Garmin Vivosport, in older adults [170]. Therefore, comparing the three different methods (the activity tracker, PPAQ and the DLW) was feasible and stimulating to explore in the FitMum study, as none of these three methods had been validated simultaneously before, nor during pregnancy.

It would have been desirable to use a research activity tracker (e.g., actiGraph) to measure MVPA, steps, and SED in the FitMum study. However, such trackers are very costly. Also, using PPAQ and PSQI at visit 4 (delivery) would have been preferable. We abstained from this to not overload the participants just after giving birth.

***Validity of the activity tracker and the Pregnancy Physical Activity Questionnaire compared to the Doubly Labelled Water***

We observed a good correlation between the activity tracker and DLW for TEE. However, to compute TEE from the tracker and DLW, we needed to estimate a large component of the energy expenditure equation, i.e., the resting energy expenditure, constituting approximately 70% of TEE [164]. This might be because the computation of PAEE from DLW is based on several assumptions [150,161]. There was a weak correlation between PAEE and PA levels from the activity tracker and DLW. Yet, compared to PPAQ-DK, we discovered that the activity tracker's PAEE estimations and DLW had a better agreement. Additionally, the PAEE from PPAQ-DK and DLW did not agree well; **Figure 2, Paper 2** shows the correlations. There is no agreement in the literature concerning the validity of CAT compared to a criterion method such as the DLW or indirect calorimetry. CATs either underestimate both TEE [171–173] and PAEE [173] or overestimate TEE and PAEE [174,175]. These contradictory results might be due to a lack of consensus and standardisations of the validity studies [176,177] and the numerous, continuously updated CATs on the market that use a variety of hardware and software [98,178].

***Comparison of the activity tracker and the Pittsburgh Sleep Quality Index***

To the best of our knowledge, no research has been published on the reliability and validity of the Garmin Vivosport for monitoring sleep during pregnancy. One study in older adults investigated three CATs for measuring sleep, including the Garmin Vivosport, and found that sleep duration was quite accurately measured [170]. Also, a systematic review examined the accuracy of Garmin activity trackers (not the Garmin Vivosport) in measuring PA and sleep and discovered two validation studies that utilised sleep diaries as the criteria method. They found that the Garmin trackers overestimated sleep time [169], consistent with our results (**Paper 4**). Generally, other brands of CAT overestimate sleep time and underestimate waking time following sleep onset when using PSG as the criteria technique [169].

We planned to validate the PSQI against the PSG, considered the "gold standard" method for studying sleep [91,92]. We were granted ethical approval and collaborated with Professor Poul Jennum, senior physician and head of the Danish Center for Sleep Medicine, Glostrup Hospital, Denmark [179,180]. This validation study aimed to have participants (n=20) wear the PSG device for one night at home and simultaneously wear the activity tracker. Then, a direct comparison between the activity tracker and the PSG could be conducted to test the activity tracker's validity in detecting sleep time and stages. However, due to COVID-19 restrictions, we could not perform this validation study. I managed to do a one-night sleep study as preparation for

this experiment. **Figures 5 and 6** show the test performed on me and a direct visual comparison between the PSG and the activity tracker for one night.

**Figure 5: Real setup of the PSG on myself in preparation for the sleep validation study.**

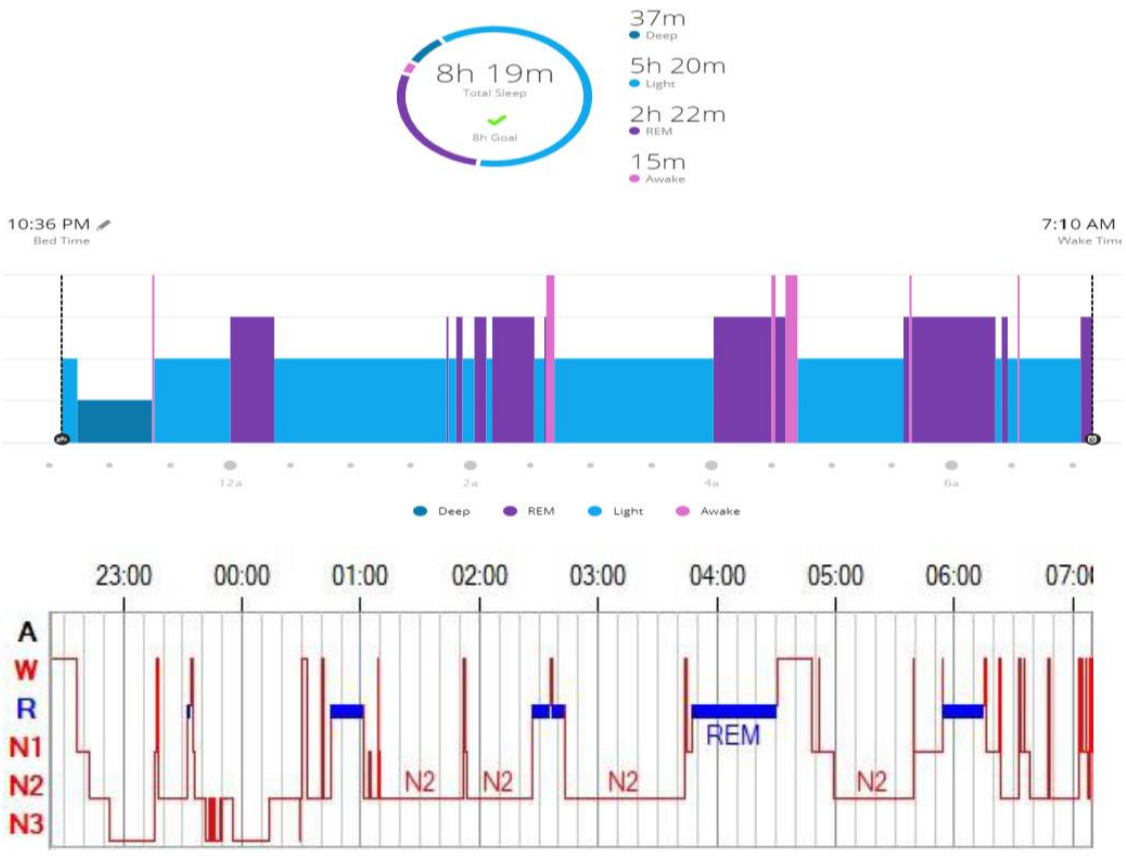


**Figure 6: A side-by-side comparison between the tracker and PSG for one night at the time of sleep.**

**The top chart is my sleep from the activity tracker, light blue is light sleep, dark blue is deep sleep, purple is rapid eye movement, and pink is waking time. The bottom chart is the PSG; W is awake time, and R and REM is rapid eye movement. N1+N2 is light sleep, and N3 is deep sleep [181]. The activity tracker measured the start of sleeping time at 22:36 while PSG measured at 22:20. The tracker also detects deep sleep well compared to the PSG. Still, the tracker missed one period of deep sleep from around 23:55 to 00:11. Moreover, compared to the PSG, the tracker underestimated waking time while sleeping and detected the most rapid eye movement periods but either overestimated or underestimated the time spent on rapid eye movement. The activity tracker tended to overestimate light sleep. The activity tracker and the PSG agreed on wake time at around 7:10.**

## Data management of the activity tracker

### *Determining wear and non-wear time for the activity tracker*

Many studies that used CAT to measure PA did not include a clear plan for handling and processing data; hence, results might be challenging to replicate and validate. Therefore, it was essential to have a pre-defined data process method for CAT to measure PA and accurately

report the findings [182]. Furthermore, it would be challenging to completely comprehend the potential for CAT to increase PA during pregnancy without methodologic transparency [110]. Contrary to an accelerometer, methods to process data from commercial PA monitors are unavailable, and a standard procedure and consensus do not exist among researchers [182]. To define wear time for the FitMum study, analysis for the primary outcomes, and other secondary outcomes from the activity tracker, we relied on previous work on the accelerometer's data process methodology [183,184], which is aligned with a recently published method concerning CAT [182]. The following section details how we handled and processed activity tracker data before the analysis, as described in the FitMum protocol paper (**Paper 1**) and the Statistical Analysis Plan [179].

As mentioned previously, the participants were instructed when included in the study to wear the activity tracker 24/7. However, there were missing data from the activity tracker for various reasons because the study was extended for a long period, i.e., 6 months on average during pregnancy plus one year after giving birth. The main reason for missing data from the activity tracker was due to not wearing the activity tracker because of skin issues, charging, forgetting, not wanting to put the activity tracker on, or dropping out of the study. We planned and pre-specified how to manage data from the activity tracker regarding valid wear time and how to calculate non-wear time in the statistical analysis plan [179]. Valid wear time was defined as 12 hours of activity tracker wear per day and four days or more of valid wear per week. Unlike the accelerometer data that can be analysed through "counts" and missing time can be detected, some CATs register particular hand and arm movements as steps [185]. Therefore, we assumed no HR recording a missing time and used the HR dataset to clean the activity tracker datasets from the non-wear time that exceeded our criteria for valid days [182]. The activity tracker captures and records HR data every 15 seconds with an optical sensor, known as photoplethysmography, by shining a green light through the skin. If the participant was not wearing the activity tracker, no recording was shown, and instated time gaps between the recording or the missing time stamp were recognisable. We used the time gaps between HR data to calculate the non-wear time for each participant each day. We developed an algorithm that I ran through all participant HR data and determined if a day had 6 hours or more of missing HR recording, i.e., the activity tracker was turned off or not on the wrist. I set the algorithm to look at HR recordings from 6 am to 12 midnight and counted the time of absence [182]. We defined activity tracker non-wear time as an interval of ≥ 5 consecutive minutes of no HR [182]. By use of the algorithm, a list of day(s) was generated for each participant when the tracker was off for more than 6 hours in a day, and we used these results to clean the datasets and remove these invalid days. In addition, we created an algorithm that captured the weeks with less than four days of valid wear time (4 days / 7 days = 57% of the week); then, a week with less than

four days would be considered a missing week (i.e., seven missing days). Each participant's week was defined as seven days from the day of randomisation to the last week before the delivery week. For participants who dropped out of the study before the delivery, a week was defined as seven days starting from the day of randomisation to the last week before the due date week. This was essential to perform the intention to treat analysis on all participants. Furthermore, due to the nature of pregnancy and that intervention ended by the day of delivery and not by completing a certain number of weeks, we applied the same criteria mentioned above to the last week of the pregnancy, i.e., the last week of the intervention. If the last week of the pregnancy had ≥ 57% of the days, the final week was included; otherwise, this final week was not representative and was considered missing. In managing the data, we did not distinguish between weekdays and weekends; however, we believe a balance of weekdays and weekends was achieved. **Figure 7** visualises one participant's activity tracker compliance (valid days).

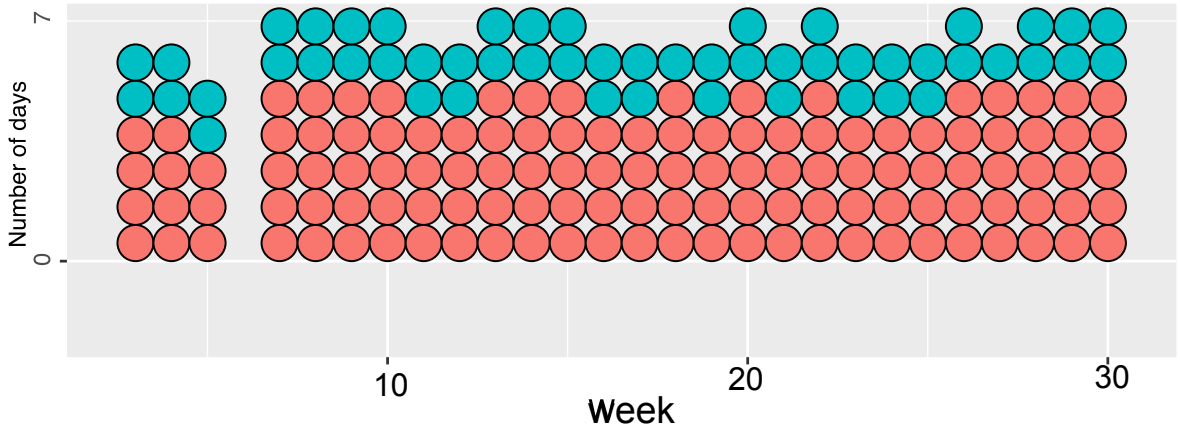


**Figure 7: Sample presentation of one participant for valid wear days/weeks. Each circle represents a valid day.**

**Red is weekdays, and blue is weekends. A column of accumulated circles represents a week.**

The data cleaning procedure required high computational capabilities as the HR dataset was huge (approx. 300 million HR observations), and a regular computer could not run this task. I used High-Performance Computing from The Danish National Life Science Supercomputing Center [186] to handle and clean the activity tracker data. I remotely accessed the supercomputer (Computerome) and performed the data cleaning in the software R [187], which has high storage and computational capabilities.

***Data preparation and imputations***

After completing the cleaning of the activity tracker data as described above, the dataset for analysing the primary and secondary outcomes included in this thesis was prepared in two steps. First, when a day with a non-wear time of more than 6 hours or a week with less than four days of valid data, this day(s) or date (Day-Month-Year) was implanted in the dataset but with a missing row of activity tracker's outcomes: Not Available or (NA). Second, multiple imputations were conducted for these NAs to estimate these missing values. Based on the assumption that data were missing at random [188], a multivariate imputation by chained equations techniques [189], preselected baseline variables (body weight, age, PA, educational level, and parity), and a random forest imputation model from the mice R package were used to impute the missing observations from the activity tracker [189]. The imputation resulted in 25 datasets we used to analyse the primary outcome of the FitMum study (MVPA), other PA outcomes, SED, and sleep.

## Statistical analyses

In **Paper 2**, we followed the current recommendations for the type of statistical analysis when validating CAT [190]. They proposed procedures and associated checklists that should be used when testing and reporting CAT or smartphone device validation. Although the proposed procedures and checklists validated energy expenditure, they can be applied to other PA outcomes. When analysing the primary outcome of the activity tracker data in **Paper 3**, intention-to-treat analysis of the covariance model (ANCOVA) adjusting for baseline using all randomised participants was performed for the primary outcome (MVPA) by a statistician blinded to the groups. In addition, we used ANCOVA to analyse other PA outcomes from the activity tracker in **Paper 3**. However, for SED and sleep from the activity tracker in **Paper 4**, since it is repeated measurements, including baseline, and because there is a correlation in the repeated measurements on the same subject, we used a constrained linear mixed model (CLMM). We compared the population means across different groups and time points after "constraining" the baseline [191]. In addition, the output of CLMM analysis was utilised to make the plots, which visually show the intervention's effect. In the CLMM plots, the baseline is a common starting point for the three FitMum study groups as it is a randomised trial [191]. Similarly, we used the CLMM for all questionnaires' analyses with a generalised additive model with a penalised regression spline with pointwise 95% confidence bands estimated by a bootstrap procedure, which was fitted with the observation times as a factor [192]. All analyses mentioned above, except the primary outcome analysis, were performed by me with the supervision of the statistician; therefore, the blindness of

the group's allocation was possible only for the primary outcome. Data are presented as means ± standard deviation for symmetric distributions and medians (interquartile ranges) for skewed data. The level of statistical significance was 5%, and confidence intervals [CI] were given for all reported estimates. The statistical analyses were performed using R version 4.2.2 [187].

# Results and discussions

## Participant characteristics

The FitMum study ran between October 2018 and May 2021. We included 220 pregnant women and randomised 219 to CON (n=45), EXE (n=87), and MOT (n=87); the FitMum study inclusion and randomisation and maternal baseline characteristics are presented in (**Figure 1 Paper 3** and **Table 1, Paper 3)**, respectively. One participant dropped out before the randomisation. There was no difference between the baseline characteristics of the randomised participants in each group. However, we observed that FitMum participants had a high level of education, with 80% at or above a bachelor's [135]. High education level is one of the most common predictors of willingness to participate in public health research [193], engaging in exercise and increasing PA during pregnancy[194,195]. Lastly, from inclusion through delivery, some participants had adverse events, including significant adverse events, but no difference between groups was found (**Multimedia Appendices 6-8, Paper 3**). A further discussion about how some of the FitMum participants' characteristics potentially impacted the PA levels, in general, will follow.

## Compliance with wearing the activity tracker

Some studies explored the compliance of wearing CATs among adults and found that CATs were worn on at least 50% of intervention days [101]. Moreover, few studies examined the acceptability and usability of CATs among pregnant women. They found that pregnant women were motivated to wear a CAT and highly satisfied with doing so during pregnancy, and the compliance of wearing a CAT ranged from 54% to 76% of potential days [102–105], which aligns with our results (77%) (**Paper 2**). The duration of the FitMum study is considerable, and the compliance with wearing the CAT is high. Two things might explain the high compliance: 1) our strict protocol of sending email reminders to the participants to sync (every seven days without sync), and 2) the two intervention groups had close contact with FitMum researchers regularly. Additionally, the high education level mentioned in the above section might indicate a willingness to participate in PA intervention and a commitment to the FitMum study's protocol regarding the activity tracker. **Figure 8** shows the compliance rate of wearing the activity tracker in the FitMum participants at three time periods during the study.

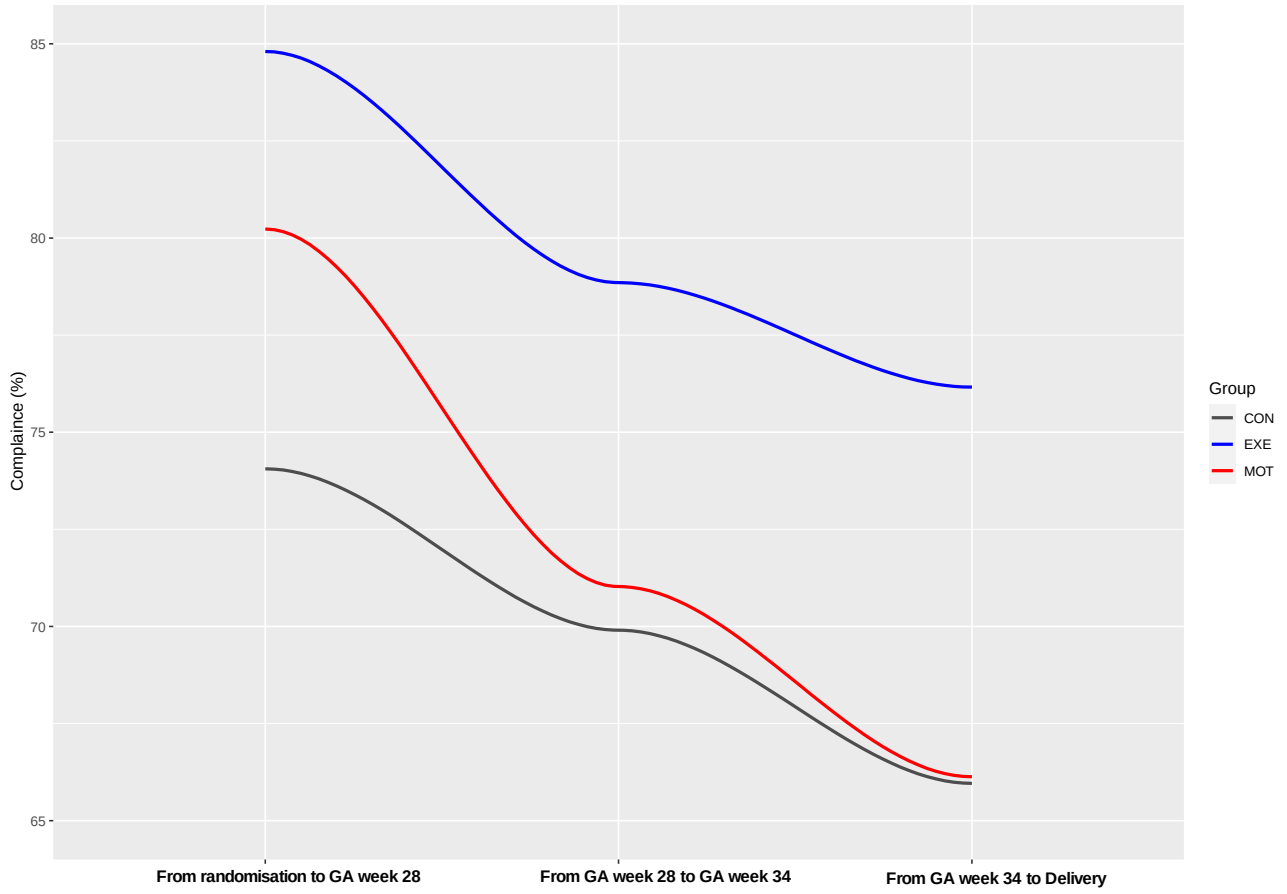


**Figure 8: The three groups' adherence to wearing the activity tracker was measured as a percentage of the potential days during the FitMum intervention.**

**Randomisation at the gestational age of a maximum of 16 weeks and 0 days; EXE: Structured supervised exercise training; MOT: Motivational counselling on physical activity; CON: Standard care.**

In general, the compliance rate from the randomisation to the delivery was 71.5% for CON, 81.7% for EXE, and 75.3% for MOT. However, the compliance rate declined drastically for the MOT group, especially after GA week 28 (from 80.2% to 71.0 %), which might be explained by fewer sessions later in pregnancy, i.e., five sessions from randomisation to GA week 28 and only two sessions from GA week 28 to delivery. Surprisingly, the CON group showed constant compliance with the activity tracker throughout the study period and was more similar to MOT at the end of the study (CON: 65.9% and MOT: 66.1% from GA week 34 to delivery). We could not investigate how much the participant interacted with the activity tracker and how they engaged with it. The compliance of wearing the activity tracker and syncing does not reflect the engagement. However, a few speculations might explain this observation of compliance between the groups with wearing the activity tracker. For instance, MOT was the group that mostly utilised the activity tracker in the counselling sessions, and PA goals were based on the activity tracker. Also, we assume that MOT used the activity tracker more extensively than other the groups; thus,

with time and challenge to reach their goals (moderate intensity), they might lose interest in the activity tracker.

## Effect of the FitMum interventions on physical activity, sedentary time and sleep measured by the activity tracker

### *Moderate to vigorous intensity physical activity*

The unadjusted MVPA (minutes/week) for CON was 33 [95% CI 18 to 47], 50 [39; 60] for EXE, and 40 [30; 51] for MOT from randomisation to GA week 28. Similarly, unadjusted MVPA (minutes/week) from randomisation to delivery was 35 [19; 51] in CON, 54 [42; 65] in EXE, and 43 [32; 55] in MOT (**Figure 3, Paper 3**). After baseline adjustment, participants in EXE performed significantly more MVPA than participants in CON from randomisation to GA week 28; 20 [4; 36] minutes per week (P=.02). Moreover, EXE participants continued to perform significantly more MVPA than CON from randomisation to delivery; 21 [3; 39] minutes per week (P=.02). Participants in EXE and MOT were able to sustain MVPA levels from randomisation to both GA week 28 and delivery, which is prone to decline as the pregnancy progressed [120]. Notably, PA at a vigorous intensity (not moderate) was higher in EXE than in both CON and MOT, which is what we believe drives the significant difference in MVPA (**Figure 3, Paper 3**, and **Multimedia Appendix 1 Paper 3**).

Moreover, since we measured MVPA continuously by the activity tracker, the effect of attending the exercise sessions daily on EXE MVPA levels was feasible to investigate. Also, we examined the impact of weekdays or weekends on MVPA (also step counts in the next section). When comparing MVPA during weekends and weekdays between the three groups from randomisation to delivery, there was no significant difference between MVPA levels on weekdays or weekend days, with -0.4 [-1; 0.1] minutes of MVPA during the weekend (P=.14). Not surprisingly, the daily MVPA levels increased when the EXE participants attended an exercise session. A comparison between the daily level of MVPA on days attending and not attending EXE sessions is presented in **Figure 9**.

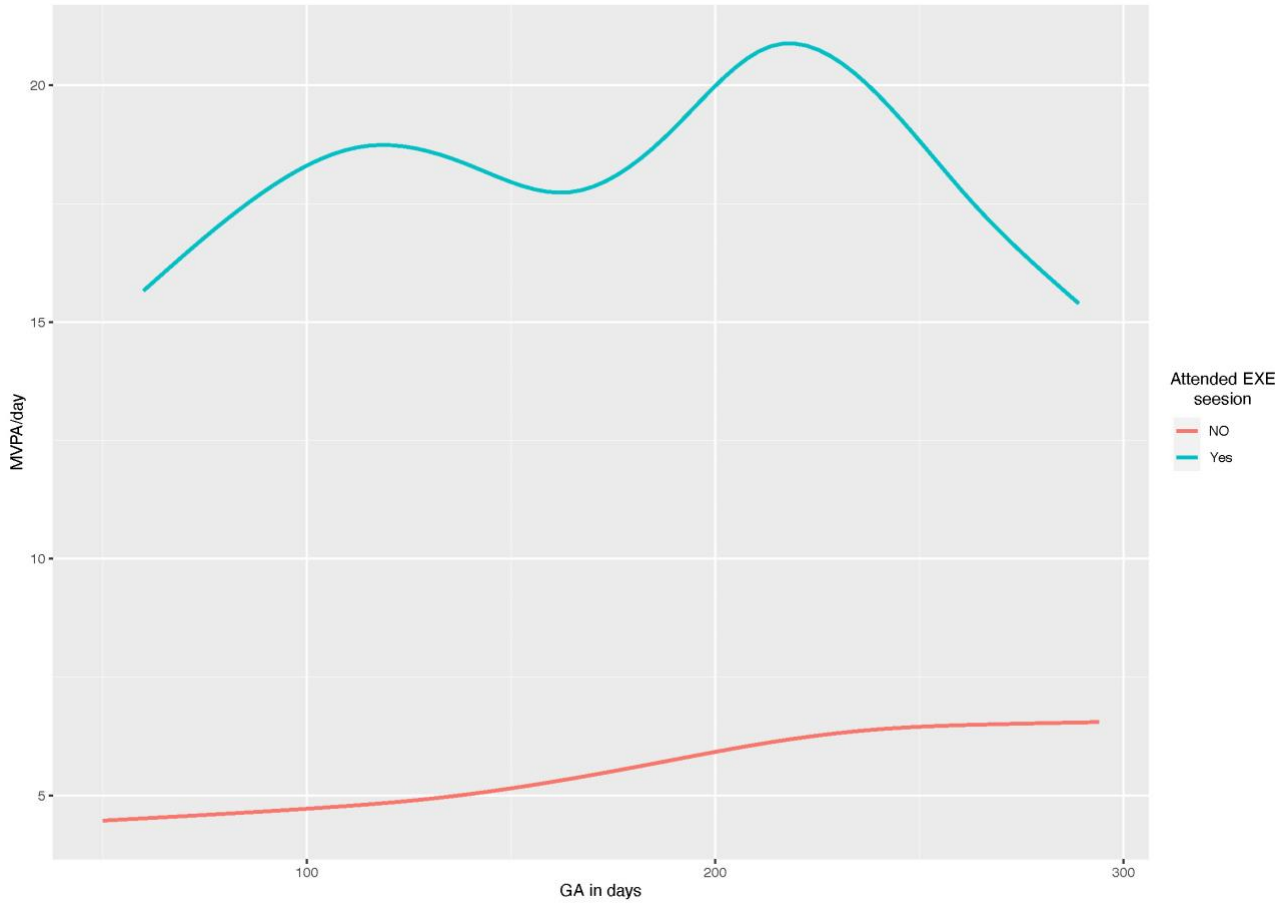


**Figure 9: A comparison between the daily level of MVPA on days attending and not attending EXE sessions.**

**Gestational age (GA) in the x-axis and mean moderate-to-vigorous intensity physical activity (MVPA) in the y-axis. Orange: days of not attending an exercise session. Green: days of attending an exercise session, n= 87.**

There was a significant increase in the daily MVPA level on days attending an exercise session (n= 87); 13 minutes more of MVPA/day [12; 14, (P = < 0.001)].

The FitMum study was the first to use CAT as a measurement tool for the primary outcome and an intervention tool during pregnancy, which might make it incomparable with other studies' results. However, this will contribute to the limited knowledge about using and utilising CATs in PA RCTs, which is highly needed [110]. In addition, using the activity tracker allowed us to measure MVPA continuously, collect the daily/weekly patterns, and capture the changes remotely, especially the primary outcome (MVPA) during the COVID-19 pandemic.

### *Steps*

The unadjusted mean steps/day from randomisation to GA week 28 for CON were 7208 [6702; 7714], 7057 [6695; 7419] for EXE, and 7174 [6812; 7536] for MOT. Unadjusted mean steps/day from randomisation to delivery were 6896 [6408; 7383] in CON, 6680 [633; 7028]

in EXE and 6792 [6441; 7143] in MOT (**Figure 3, Paper 3)**. When adjusted for baseline, there was no significant difference between groups (**Multimedia Appendix 1, Paper 3)**.

A higher number of steps per day, which can be increased by walking during commuting or leisure time, might reduce the risk for several adverse health outcomes during pregnancy, such as gestational diabetes, preeclampsia, and excessive weight gain [196–199]. Steps are the most measured and reported in PA interventions during pregnancy due to the simplicity of the measurement, especially with a pedometer, and less experienced as a barrier among pregnant women [199]. In the FitMum study, most of the PA automatically detected by the activity tracker's Move IQ function was walking (**Figure 10**).

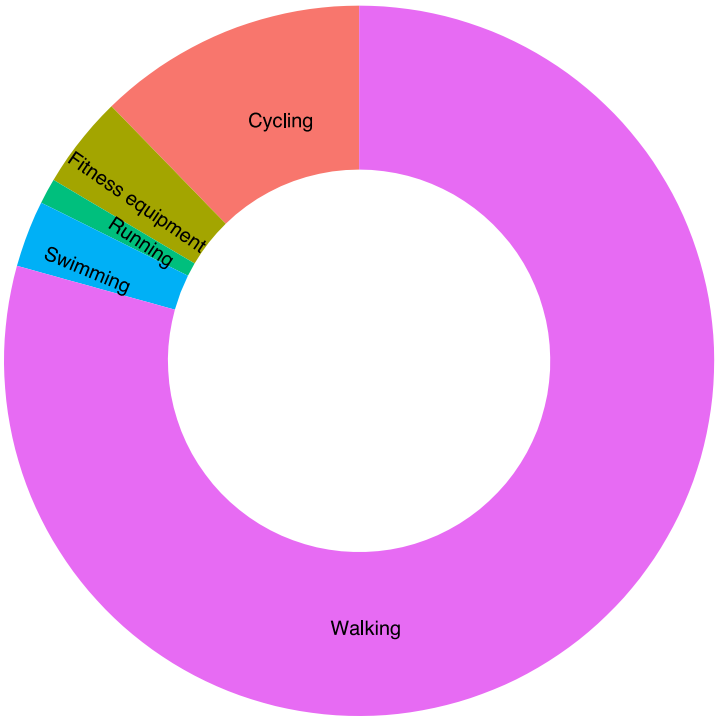


**Figure 10: The Garmin Vivosport Move IQ function. Move IQ captures a period of movement corresponding to specific PA patterns, such as bicycling, running, swimming, walking, or using an elliptical machine [200].**

**The activities shown in the figure are percentages of the frequency of the activity captured automatically from randomisation until delivery, n= 209. Colours: pink = walking (79.3%); red= cycling (12.3%); gold = fitness equipment (4.2%); blue= swimming (3.0%); green= running (1.2%).**

Therefore, future PA interventions using CAT or other step measurement tools might also focus on increasing the number of daily steps or brisk walking at a moderate-intensity level

[199]. Lastly, when we examined the impact of weekdays or weekends on steps per day, participants had 120 fewer steps during the weekend days [-240; -0.6, (P=.049)].

***Modest effect of FitMum interventions***

The results of the FitMum study are similar to the trials that found PA interventions to modestly increase PA or MVPA levels among pregnant women [121,131,201]. In a recent systematic review and meta-analysis of 18 PA RCT studies using device-based measurements, e.g., accelerometer and pedometer, Sharp et al. found that from baseline to mid-pregnancy, participants (n=1934) who were randomly assigned to a PA intervention group achieved 34.2 minutes more MVPA/week than the comparison group [201]. Similarly, Sharp et al. investigated the steps/day at GA week 24 to 30 in seven RCTs and found that, on average, the intervention group achieved 7299 steps/day compared to 6162 steps/day in the control. We could not find significant differences after adjusting the steps/ day baseline and comparing the groups from randomisation to GA week 28 and delivery. The number of steps/days was considerably high in the three groups. In the FitMum study (at GA week 28), EXE achieved 7057 steps/day, which is comparable to the intervention groups in the review by Sharp et al. However, CON reached 7208 steps/day, which is 1046 more steps/day than the control groups in the same review.

The following might explain the modest effect of the FitMum interventions on MVPA levels and no effect on steps. Firstly, there might be an unbalanced MVPA baseline between the groups, which we did not test for significance as it is not recommended for RCTs [202]. Secondly, the default for the activity tracker reported activities with a MET value of ≥3 in bouts of at least 10 consecutive minutes as MVPA; hence, MVPA bouts of less than 10 minutes are not captured. Thirdly, CON participants also sustained the MVPA levels throughout pregnancy (33 and 35 min/week of MVPA at GA week 28 and delivery, respectively). Also, CON steps achieved a high number of steps compared to EXE and MOT during the intervention at the baseline. Fourthly, the focus of the FitMum study on MVPA in the two intervention groups might drive attention to PA intensity rather than increasing PA in general. Lastly, FitMum participants volunteered and signed up to FitMum because they were interested in PA; 91% said they wanted to join the FitMum study to raise their PA levels [135]. As shown in the compliance section, the compliance of wearing the activity tracker in all groups was relatively high, surprisingly for CON, which might support the argument that we included highly motivated pregnant women. Therefore, CON being physically active might account for the minimal variation in MVPA between EXE and CON, which could be true for other FitMum study PA outcomes. Nevertheless, the increase in

MVPA level during pregnancy due to PA interventions, such as in FitMum, is usually below the recommended level but may have a beneficial effect on health [117,119,201,203].

***Sedentary time***

We did not see significant differences between the groups in SED (**Figure 3, Paper 4)**. However, we observed a trend that, with time, the average SED for all participants significantly increased (P <.001) by approx. 24 min/day from baseline to delivery. A systematic review investigating sedentary behaviours during pregnancy found that despite the wide disparity between sedentary behaviour definitions and measurement techniques, pregnant women spent more than half of their day sedentary [4], and sedentary behaviour increased as the pregnancy progressed [58,204], which was also seen in the FitMum study. SED is briefly mentioned in some PA guidelines for pregnant women, with no clear guidance on reducing SED and the time limit [6]. Although MVPA might be met or sustained during pregnancy, as we observed in the FitMum study, and in a few other studies [58,205], SED is overlooked in lifestyle interventions during pregnancy. Future research should employ reliable methodologies, ideally with an objective method for assessing SED, and investigate the association between SED and maternal and neonatal outcomes [4,204,206].

***Sleep***

In **Paper 4,** we did not find significant differences between the groups in sleep time (**Figure 3, Paper 4)**. When we investigated the time effect (pregnancy progression) on sleep time, we found that the average sleep time decreased significantly (P<.001) from baseline to GA week 28, to GA week 34 and to delivery by approx. 12, 18 and 30 min/day, respectively. To the best of our knowledge, previous RCTs examining the impact of PA on sleep in pregnant women did not use objective methods to measure sleep time [33,166]. Kominiarek et al, in an observational study, explored pregnancy sleep duration using a CAT (Fitbit Flex). In line with our findings, they found that as the pregnancy progressed, there was a significant inverse association between time and sleep [207]. Our findings that sleep time worsens as the pregnancy progresses are aligned with recent systematic reviews and meta-analyses [12,43]. Sleep disturbance starts as early as the first trimester and might continue after giving birth, requiring attention from researchers and medical care providers [208]. Therefore, interventions that include regular PA and measured sleep by valid methods (e.g., PSG) are highly needed [33,209].

Finally, both results that sleep time decreased and SED increased are aligned with the trend during pregnancy regarding the two behaviours. It highlights the importance of objective measurement of physical behaviour and the potential of CAT to detect these trends.

## COVID-19 pandemic's impact on physical activity, sedentary time, and sleep

A comparison was made on the MVPA level between participants included before the COVID-19 pandemic who received the physical intervention only (n=120) and during the COVID-19 pandemic who received the online intervention only (n= 63). Although EXE participants who were offered the online intervention attended more exercise sessions per week than their counterparts that were offered the physical intervention (physical: 1.1[ 0.9; 1.4]; online: 1.6, [1.3; 2.0], P=.03). MVPA level (minutes/week) was not impacted by the COVID-19 pandemic in the EXE group specifically, and not in MOT and CON either (**Multimedia Appendix 2, Paper 3**). However, EXE participants who received the online intervention had more SED from randomisation to delivery than EXE participants who received the physical intervention (**Figure 4, Paper 4**). During the COVID-19 pandemic, some studies explored the impact of the pandemic on PA and SED. For instance, during the pandemic in the United Kingdom, the United States of America, and Denmark, due to fear of getting infected and the restrictions imposed by the health authorities, SED increased, and PA decreased [210–212]. Moreover, a single-arm remotely delivered health coaching intervention to increase PA and reduce SED was conducted among pregnant women. The study showed that PA significantly increased, and SED significantly decreased as measured by activPAL3 micro from baseline compared to the end of the intervention (GA week 22-28) [213]. This aligns with our findings, although shifting the intervention online did not significantly lower MVPA (**Multimedia Appendix 2, Paper 3**). These results might highlight the potential and benefit of incorporating both physical and online PA interventions while focusing on SED reduction during pregnancy. A remote intervention combined with CAT utilisation proved feasible and acceptable and can improve physical behaviour during pregnancy [213]. Yet, the adoption and effectiveness of combining interventions (i.e., physical plus online attendance) in lifestyle interventions during pregnancy need further and rigorous assessment [214–216].

## Effect of FitMum interventions on energy expenditure and physical activity measured by the Doubly Labelled Water

The DLW analysis was performed once during FitMum (n=134) at GA week 28. The total energy expenditure, the active energy expenditure, and the PA level showed no significant difference between the groups (**Multimedia Appendix 5, Paper 3**). Although DLW has previously been used to estimate PA levels in pregnant women [165], to our knowledge, the FitMum study is the first intervention study in pregnant women to utilise DLW. As mentioned earlier, DLW does not capture PA intensity; thus, no difference in the overall activity across groups was found. This aligned

with what we found with the other methods used in the FitMum study, with no differences between groups' PA levels from the activity tracker in active calories/day (**Figure 3, Paper 3** and **Multimedia Appendix 1, Paper 3**) and total activity MET-h/week (**Figure 6, Paper 3** and **Multimedia Appendix 3, Paper 3**). However, from DLW, and since we can derive total body water and then compute body composition, there is an ongoing investigation by the FitMum study researchers to investigate the maternal body composition during pregnancy using DLW.

## Effect of the FitMum interventions on physical activity, sedentary time and sleep measured by the questionnaires

***Physical activity and sedentary time from the Pregnancy Physical Activity Questionnaire***

In contrast to the activity tracker, MVPA from PPAQ-DK showed no difference between groups, but the participants in MOT reported significantly high PA at a vigorous intensity from baseline to GA week 28 and from baseline to GA week 34, respectively (mean difference MET-h/week: -2 (P=.002), 1 (P=.03) (**Multimedia Appendix 4, Paper 3**). Additionally, EXE reported significantly higher MET-h/week in sport compared with CON and MOT at both GA week 28 and GA week 34. At the GA 28 week, PPAQ-DK showed that the EXE group had lower SED compared to CON (approx. -17 min/d) and compared to MOT (approx. -14 min/d) (**Figure 2, Paper 4**). Lastly, the average SED of the FitMum participants decreased by 1.1 hr/day from baseline to GA week 34.

***Inconsistent results of physical activity and sedentary time between activity trackers and the Pregnancy Physical Activity Questionnaire***

The PPAQ-DK results in our study contradicted the activity tracker, where MVPA differences were detected by the activity tracker but not PPAQ-DK and PPAQ-DK showed differences in SED but not MVPA. The following rationalises these inconsistent observations. With the acknowledgement of self-report bias and the fact that individuals overestimated PA and underestimated SED when reported by the questionnaire, we saw an overestimation of MVPA from PPAQ-DK compared with the activity tracker (**Paper 2**). This overestimation is also observed in MOT, as they significantly increased PA at vigorous intensity from baseline to GA week 28 and to GA week 34, according to PPAQ-DK (**Figure 6, Paper 3 and Multimedia Appendix 4, Paper 3)**, but not from the activity tracker. Although PPAQ is widely used to measure PA during pregnancy, PPAQ-DK has not been used before in an RCT. We validated the PPAQ-

DK before the FitMum study started, but the validity and reliability of questionnaires in measuring the impact of PA interventions in repeated measurement setup have yet to be established [137].

Regarding SED, PPAQ underestimated SED compared to objective measurements [70]. We observed a similar pattern with PPAQ-DK compared to the activity tracker (**Paper 2**). Also, other RCTs that used PPAQ showed an increase in PA levels among the exercise groups but no significance in SED [217–219]. Our results were considered distinct in many ways. We followed the new recommendations of including three more questions (five in total) instead of the original two to compute SED from PPAQ. To our knowledge, we are the first to use this approach in a PA RCT among pregnant women. We believe this may increase PPAQ- DK's sensitivity to capture any differences between groups. Moreover, the PA dose was well delivered with high fidelity [135], which might influence EXE participants' perception of SED, thus subjectively reporting less SED than MOT.

Lastly, there is a discussion among scholars in the field of PA measurements during pregnancy [89,167]. The argument is that questionnaires might be not the right tool to measure PA interventions' impact or health outcomes. Rather questionnaires such as PPAQ are designed and should be used for ranking PA among a large number of pregnant women, such as for surveillance purposes. In a commentary, Guérin et al. built an argument around objectively measuring PA during pregnancy. They addressed the limitations of questionnaires in measuring PA during pregnancy, and that research should consider objective measurement to test the impact of PA on women's health [89]. As Chasan-Taber et al. (PPAQ developer) explained, in a letter responding to the Guérin et al. commentary, the motivation to design PPAQ was to create a list of activities that were the most significant drivers of between-person variance to categorise pregnant women into PA categories accurately[167]. Furthermore, Chasan-Taber et al. are working on updating and improving this widely used self-report tool by using novel validation methods to assess PPAQ performance in free-living settings and enhance SED measurements [155]. This discussion stimulates researchers to work more on developing and validating reliable tools for PA and SED measurements during pregnancy.

***Sleep measured by the Pittsburgh Sleep Quality Index***

All three groups in the FitMum study started the study with poor sleep (mean = 6.4 ± 1.9), which is aligned with other findings among pregnant women [12,220,221]. EXE scored lower (lower is better) in the global PSQI score at GA week 28 and GA week 34 than CON. Also, MOT scored lower than CON at GA week 34 (**Paper 4, Figure 1**). At GA week 34, EXE had shorter sleep latency and less sleep disturbance than CON. In addition, EXE had lower daytime

dysfunction than MOT at GA week 28. A complete comparison between the three groups is shown in **Paper 4, Table 1**. Our results are aligned with systematic reviews and meta-analyses of RCTs conducted among pregnant women that used the PSQI [33,166]. These reviews showed that PA level was positively associated with sleep quality as determined by PSQI during pregnancy, and exercise participants had significantly improved sleep quality compared to the controls. In the FitMum study, EXE and MOT had better sleep quality than CON, adding essential findings to the limited knowledge about PA interventions and sleep quality during pregnancy. Furthermore, when exploring the time effect on all participants, sleep time decreased by approx. 14 minutes/day from baseline to GA week 34; the activity tracker reported 18 minutes/day. Therefore, sleep disturbance is high during pregnancy and needs more attention and investigation.

***Mechanism of the impact of physical activity on sleep quality and quantity***

The underlying mechanisms associated with PA and sleep are still unrevealed [222]. PA is thought to improve sleep quality and quantity in several ways [223,224]. One mechanism is through a hormonal, thermoregulatory, and neurological mechanism that PA brings, which promotes sleep [224]. For instance, growth hormones released during and after PA can help to reduce stress and promote relaxation. Another mechanism is the regulation of circadian rhythms. Regular PA can help regulate the body's internal clock, which regulates sleep-wake cycles. This can help to improve the timing and duration of sleep, leading to better sleep quality and quantity [223,224]. Furthermore, regular PA effectively enhances sleep quality and quantity during pregnancy, specifically at moderate intensity and when structured 1-3 times a week [33,34,225]. However, there is an urgent need for rigorously designed studies investigating how sleep and PA are related and the interplay with pregnancy outcomes [166,226].

## Compositional analysis and the 24-hour movement

We performed a compositional data analysis to explore the percentage of time spent in activity, SED, and sleep over 24 hours (**Figure 11**).

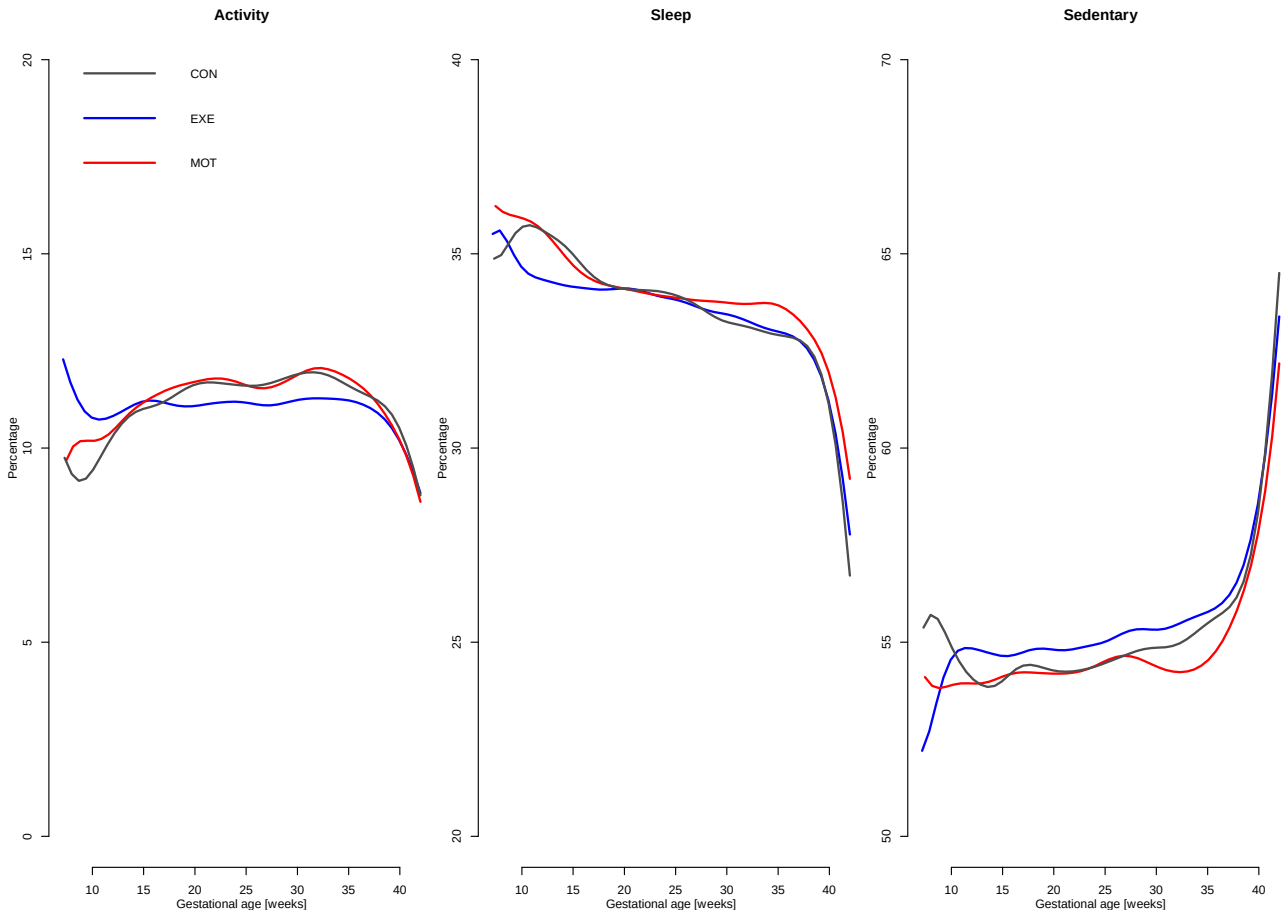


**Figure 11: Compositional data analysis. All 219 women in the FitMum study were included in this compositional analysis.**

**We used the imputed data to plot time spent on the three physical behaviours. SED and sleep time are calculated as described in the method section. Active time was computed by subtracting SED and sleep time from 24 hours. Since we included pregnant women before GA 15 weeks, we might have a few women in the first weeks in the x-axis. Also, since birth happened at or before GA 40 weeks, few were at the end of the x-axis.**

We tested the composition of the 24 hours between the groups and found no significant differences. Out of the 24 hours, the participants spent approximately 12% active, 34% in sleep, and 54% sedentary in early pregnancy, corresponding to 2.8, 8.2, and 13.0 hr/day, respectively. Furthermore, in late pregnancy (after GA week 34), activity dropped by 2-4% and sleep by 3-6%, and SED increased by 3-6%. Very limited studies have examined the 24-hour movement during pregnancy or used the compositional data analysis approach [53,227]. Badon et al. applied compositional analyses in early and late pregnancy in 155 individuals with pre-pregnancy overweight or obesity. They found that participants spent 26.6% active, 33.8% sleep, and 36.9% SED in early pregnancy (GA week 8-15), corresponding to 7.0, 8.1, and 8.9 hr/ day, respectively. In late pregnancy (GA week 29-38), activity increased by 4%, sleep time dropped by 1.7%, and

SED increased by 0.3%. Our result might not be comparable to Badon et al because they used accelerometry to measure PA and SED and self-report to measure sleep. Also, PA and SED were measured twice during pregnancy for seven days each (GA 8–15 and 29–38 weeks) and not continuously as we did with the activity tracker.

Furthermore, the 24-hour movement and the compositional data analysis approaches are emerging. Technological and statistical advancement allows researchers to associate physical behaviour composition and health risk. Sandborg et al. were the first to investigate the composition of 24-hour movement and cardiometabolic health in early and late pregnancy [227]. They found that in early pregnancy, lower body weight and better cardiometabolic health were associated with the reallocation of SED and sleep time spent into light PA or of SED and light PA into MVPA. Lastly, future interventions should aim to improve and investigate the 24-hour movement profile change over the course of pregnancy [53,227]. Interestingly, the apparent changes in the distribution of time between activity, sleep, and SED at the end of the pregnancy indicate that it might be possible to predict the time of birth or initiation of the labour by the activity tracker. We are currently investigating if we can predict labour time using machine learning techniques with our collaborators at The Technical University of Denmark.

# Conclusions and perspectives for future research

The main objective of this PhD thesis was to examine the effects of two different PA interventions offered to healthy inactive pregnant women on PA, SED, and sleep. As the thesis is based on data collected by various methods to measure PA, SED, and sleep, a comparison of these methods was explored. The following are narrative conclusions of all manuscripts included in the thesis and perspectives for future research.

The primary outcome of the FitMum study was MVPA, measured by the activity tracker from randomisation to GA week 28. In addition, other PA data, SED, and sleep measured by various methods were explored. When measured objectively by the activity tracker, pregnant women receiving EXE engaged in more MVPA than those offered CON from randomisation to GA week 28 and delivery. Also, there were no differences in levels of MVPA between pregnant women in MOT and CON and between EXE and MOT. The results support our hypothesis that EXE is more effective than MOT in increasing MVPA but reject the hypothesis that MOT is more effective than CON. Although EXE sustained MVPA levels during pregnancy, they did not reach the recommended 210 minutes/week. PA minutes/week at vigorous intensity was higher, and the driver for MVPA, in EXE compared to both CON and MOT. There were no differences in other PA outcomes measured by the activity tracker. Future studies should explore how to increase PA to reach the recommended levels in diverse pregnant women. Furthermore, RCTs with PA interventions during pregnancy might include and investigate simple and achievable goals like increasing daily steps (e.g., walking at moderate intensity) and utilising a wearable (e.g., CAT and accelerometer) to enhance the validity and reliability of findings.

Additionally, the activity tracker measured SED and sleep time during pregnancy and showed no differences between the groups. However, the activity tracker showed a trend toward more SED and less sleep time as the pregnancy progressed. Hence, future PA interventions should focus on SED, sleep, and the interaction between the pregnancy's 24-hour movement and maternal and neonatal health. Since there is no clear guidance or specific time recommendations for SED and sleep during pregnancy, studies are needed to generate evidence-based guidelines on the best strategies to reduce SED and improve sleep. Moreover, future studies should design RCTs powered to detect the impact of PA interventions on SED and sleep objectively and to explore how PA affects sleep during pregnancy.

COVID-19 pandemic restrictions and shifting the interventions online did not affect MVPA or sleep time but increased exercise participation. Participants in EXE receiving the online intervention had more SED than those EXE receiving the physical intervention. Therefore, future

studies should explore the effectiveness of remote or a combination of physical and remote exercise interventions to increase PA and reduce SED.

Outcomes from the DLW analysis showed no differences between the groups regarding PA levels and energy expenditure. However, DLW data from the FitMum participants will be used to investigate maternal body composition. Future studies utilising DLW in PA intervention studies among heterogenous pregnant women are needed. When PA was reported subjectively using PPAQ-DK, there were no significant differences between the groups in MVPA levels. However, MOT reported increased vigorous PA levels from baseline to GA week 28 and GA week 34. PPAQ-DK showed that total activity and SED decreased from baseline to before the delivery for all groups. Self-reporting tools that measure PA and SED during pregnancy need rigorous validation and updating. Furthermore, EXE and MOT had better sleep quality than CON during late pregnancy, but sleep time decreased for all participants, as reported by PSQI. During pregnancy, healthy sleep patterns need more attention from clinicians and PA researchers.

The activity tracker performed better than PPAQ-DK when compared with DLW in measuring PAEE. The activity tracker consistently measured lower PA and higher SED during pregnancy than what was reported by PPAQ-DK. Measuring PA, SED, and sleep during pregnancy is complicated, and combining subjective and objective tools offered comprehensive findings. Consequently, PA and SED findings were inconsistent in the FitMum study. Rigorous studies using objective, valid, and reliable physical behaviour measurement tools during pregnancy are warranted. CAT is becoming more popular, acceptable, and feasible in monitoring prenatal health and measuring physical behaviour during pregnancy. Moreover, with a high compliance rate, the activity tracker in the FitMum study detected the impact of the interventions on MVPA levels and identified SED and sleep trends during pregnancy. Therefore, using CAT in PA interventions may accelerate evidence-based knowledge about tailoring and remotely delivering lifestyle-changing interventions. This may even strengthen the prediction and prevention of maternal and neonatal adverse health outcomes. However, the developments and adoption of CAT in physical behaviours studies during pregnancy are limited by the CAT validity and constant update of hardware and inaccessible algorithms.

Finally, PA, SED, and sleep after giving birth are not less important than before giving birth, and this is worth exploring. Participants in the FitMum study were encouraged to wear the activity tracker after delivery for one year. Also, PPAQ-DK was utilised to measure PA, SED, and PSQI for sleep one year after giving birth. PA, SED, and sleep for one year postpartum will be investigated to see the overall trend of these behaviours and if the FitMum impact is maintained.

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# Appendixes

# 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

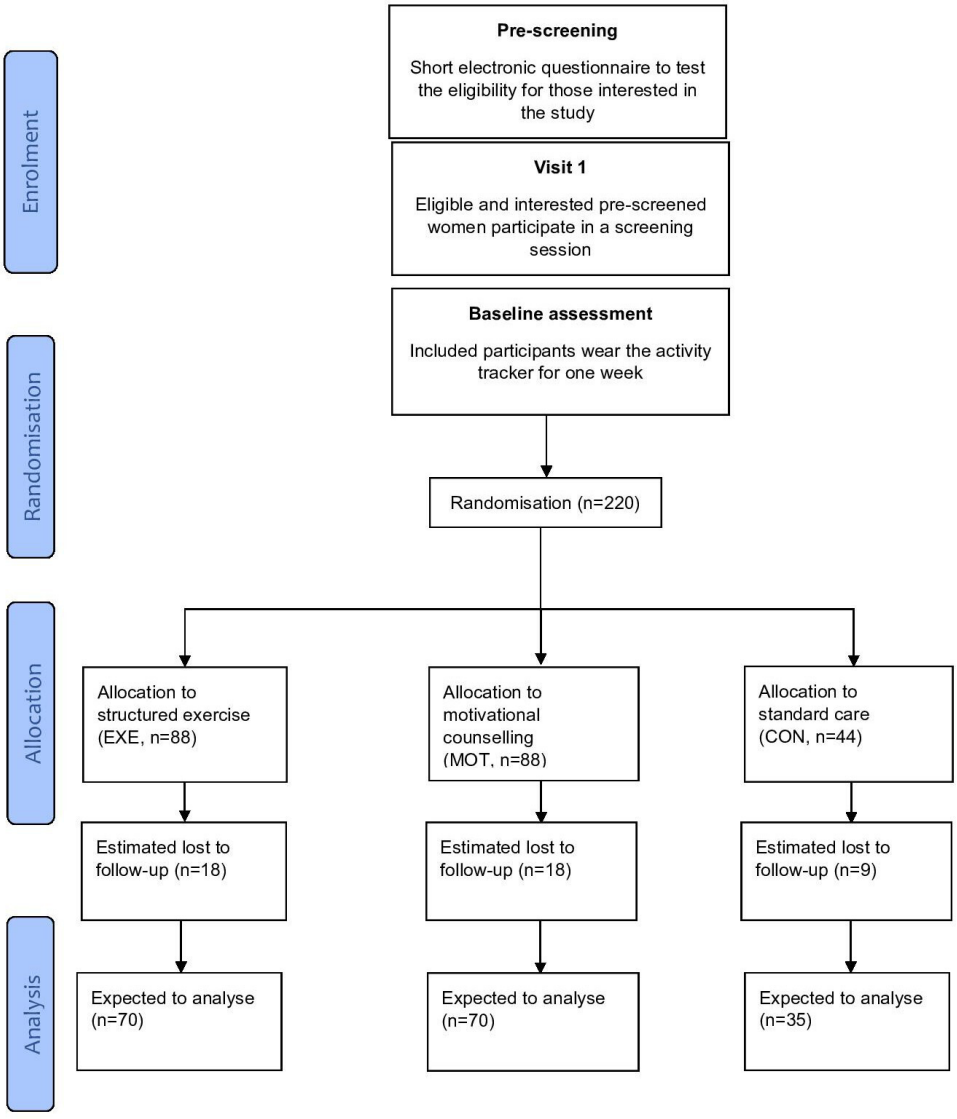


**Figure 1** Flow diagram of the FitMum RCT.

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 | |
|---|---|---|---|---|---|---|---|
| | | | | | Delivery | | |
| Gestational age (week+days) | Screening and baseline testing max. 15+0 | One week after inclusion | Week 28+0–6 | Week 34+0–6 | 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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# Paper 2

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Human Kinetics
ORIGINAL RESEARCH

# Methods to Estimate Energy Expenditure, Physical Activity, and Sedentary Time in Pregnant Women: A Validation Study Using Doubly Labeled Water

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***Background:*** Activity trackers and the Pregnancy Physical Activity Questionnaire (PPAQ) measures physical activity (PA) and sedentary time (SED). However, none of these tools have been validated against a criterion method in pregnancy. We aimed to compare a consumer activity tracker and the Danish version of PPAQ (PPAQ-DK) and to validate them using the doubly labeled water technique (DLW) as criterion method. ***Methods:*** A total of 220 healthy pregnant women participated. Total energy expenditure (TEE), PA energy expenditure (PAEE), and PA level were determined at gestational Weeks 28–29 using DLW and a Garmin Vivosport (Garmin, Olathe, KS) activity tracker. In addition, PAEE, moderate-to-vigorous intensity PA, and SED were determined using the activity tracker and PPAQ-DK during all three trimesters. ***Results:*** TEE from the activity tracker and DLW correlated ($r = .63$; $p < .001$), but the activity tracker overestimated TEE (503 kcal/day). Also, the activity tracker overestimated PAEE (303 kcal/day) and PA level compared with DLW. Likewise, PPAQ-DK overestimated PAEE (1,513 kcal/day) compared with DLW. Compared to PPAQ-DK, the activity tracker reported lower values of PAEE and moderate-to-vigorous intensity PA and higher values of SED during all three trimesters. ***Conclusions:*** When compared to DLW, we found better agreement of PAEE estimates from the activity tracker than from PPAQ-DK. TEE from the tracker and DLW correlated moderately well, but this was not the case for PAEE or PA level. The activity tracker measured lower PA and higher SED than PPAQ-DK throughout pregnancy. The consumer activity tracker performed better than the questionnaire, but both significantly overestimated PA compared to DLW.

***Keywords:*** consumer activity tracker, pregnancy physical activity questionnaire

Physical activity (PA) during pregnancy lowers the risk of complications during and after pregnancy, such as high blood pressure, gestational diabetes, and excessive gestational weight gain (Committee on Obstetric Practice, 2015; Evenson et al., 2014; Mottola et al., 2018; Moyer et al., 2016; Perales & Artal, 2017). The World Health Organization recommends that pregnant women be physically active at moderate intensity for at least 150 min/week and reduce their sedentary time (SED; Bull et al., 2020). Guidelines should be based on valid and reliable measurements of PA and SED, but estimates of PA and SED vary between different measurement tools (Fazzi et al., 2017; Strath et al., 2013). Considerations for the selection of a measurement tool include the purpose (e.g., surveillance and assessment of the effectiveness of an intervention), the variables of interest (e.g., total activity levels and energy expenditure), and practical factors (e.g., numbers of people being measured and cost; Strath et al., 2013).

Activity trackers offer objective measures of PA and SED via accelerometers and physiological sensors (e.g., heart rate; Wright et al., 2017). Activity trackers can estimate energy expenditure as well as PA duration, frequency, and intensity (e.g., moderate-to-vigorous intensity PA; Düking et al., 2018; Wright et al., 2017). Additionally, some activity trackers can recognize different types of activities, for example, walking, running, or cycling (Wright et al., 2017). Many consumer activity trackers are placed on the wrist and can be linked to an app or a platform to review the acquired data, assess data quality, and plan and deliver an intervention; in addition, data can be extracted for analysis (Wright et al., 2017). From a research perspective, there are a number of limitations associated with consumer activity trackers, including proprietary software and algorithms, and unknown details of software updates (Shei et al., 2022; Wright et al., 2017). While previous research studies have

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demonstrated relatively good accuracy of activity trackers in estimating total energy expenditure (TEE; O'Driscoll et al., 2020), there is a lack of rigorous and standardized validation of these devices in free-living settings (Argent et al., 2022; Düking et al., 2018). Also, no previous studies have validated the performance of activity trackers against the doubly labeled water (DLW) technique in pregnant women (Sattler et al., 2018).

DLW is expensive but is considered the "gold standard" for measuring TEE in free-living humans. The technique is based on the principle that the disappearance rate of the heavier stable isotope of hydrogen ($H_2$) reflects the water turnover rate and the disappearance rate of the heavier stable isotope oxygen ($^{18}O$) reflects both water and carbon dioxide ($CO_2$) turnover rates. Therefore, with time, the difference between the disappearance rates of $H_2$ and $^{18}O$ represents the rate of $CO_2$ production. Based on the energy equivalent of $CO_2$, TEE can be estimated by the rate of $CO_2$ production. The energy expended due to PA (PAEE) can be calculated from TEE (Westerterp et al., 2013) by subtracting the basal metabolic rate and the thermic effect of food.

Self-report questionnaires on PA are convenient and inexpensive and have shown acceptable reliability but low validity against accelerometers, pedometers, and diaries for pregnant women (Sattler et al., 2018; Schuster, 2016). The Pregnancy Physical Activity Questionnaire (PPAQ) was developed to assess PA specifically during pregnancy. PPAQ is a self-administrated, semiquantitative questionnaire with 32 questions designed to measure the duration and intensity (sedentary, light, moderate, and vigorous) of activities from various domains (household, occupation, transportation, and sport; Chasan-Taber et al., 2004). The Danish version of PPAQ (PPAQ-DK) has demonstrated acceptable reliability for measuring PA among pregnant women (Krøner et al., 2020), and the validity of PPAQ to measure total PA and SED using wrist-worn Actigraph GT3XP-BTLE (ActiGraph) and a wearable camera is currently being investigated by the author of the original tool (Grantome, n.d.). However, relying on only questionnaires, such as PPAQ, to measure the effectiveness of an intervention is not recommended (Sattler et al., 2018; Schuster, 2016). PPAQ has been validated against accelerometers (Chandonnet et al., 2012) and pedometers (Çırak et al., 2015) but estimates of PAEE, moderate-to-vigorous intensity PA, and SED obtained by PPAQ have not previously been compared with a consumer activity tracker or validated against DLW (Krøner et al., 2020).

The FitMum study aims to explore strategies to increase PA during pregnancy in women with low PA, and assess the health effects of PA (Knudsen et al., 2022; Roland et al., 2021). The primary outcome was moderate-to-vigorous intensity PA as measured by a Garmin Vivosport activity tracker. In addition, PPAQ-DK was used to assess PA practices among FitMum women. However, none of the tools have been validated against a criterion method in pregnancy. Thus, the present study aimed to validate TEE, PAEE, and PA levels using the Garmin Vivosport activity tracker and PAEE from PPAQ-DK against the DLW technique as the criterion method in pregnant women from the FitMum study. Moreover, we compared PAEE, moderate-to-vigorous intensity PA, and SED measures from the activity tracker and PPAQ-DK.

# Methods

## Setting, Participants, and Study Design

The study was part of the FitMum randomized controlled trial conducted at the Department of Gynaecology and Obstetrics, Copenhagen University Hospital—North Zealand, Hillerød, in the Capital Region of Denmark (Roland et al., 2021). Two hundred and twenty healthy, inactive (< 60 min/week of structured moderate-to-vigorous intensity PA) pregnant women were enrolled before gestational Week 15 (Visit 1). The first participant was included on October 1, 2018 and the last participant gave birth at the end of May 2021. After a 1-week baseline period, participants were randomized to one of two different PA interventions or standard care throughout pregnancy. In the 29th and the 35th gestational weeks, Visits 2 and 3 took place. Figure 1 presents the methods used and time points of the data collection.

## Doubly Labeled Water

DLW was administered at Visit 2 to 134 participants. The DLW test was made available to interested participants until we ran out of DLW supply (due to economic reasons). Two baseline urine samples were collected for the determination of background enrichment. The DLW (Sercon Limited) was obtained from two larger batches containing $D_2O$ (99.8% enrichment) and $^{18}O$ (10% enrichment). The participant's body weight was measured and the participant was administered a glass of water for oral intake of 0.1 g of 99.98 % $D_2O$ and 1.6 g of 10% $^{18}O$ per kg body weight. The exact date and time of DLW intake were recorded. Aliquot doses of DLW were saved at −80 °C as reference samples. During the following 2 weeks, the participant collected a single urine sample of at least 10 ml in the morning (not the first void) after 1, 4, 7, 11, and 14 days. Each participant recorded the exact date and time of the void. Participant compliance was excellent; only five participants missed one urine collection and two participants missed two or three collections. The participants were instructed to keep the samples at −20 °C after collection, and the samples were transported to Copenhagen University Hospital—North Zealand as soon as possible after Day 14 for storage at −80 °C. Analysis of the samples was performed at Clinical Metabolomics Core Facility, Copenhagen University Hospital—Rigshospitalet.

$^{2/1}H_2$ and $C^{18/16}O_2$ were determined by isotope ratio mass spectrometry using a Thermo Delta V Advantage continuous-flow isotope ratio mass spectrometer system equipped with a Thermo GasBench II (Thermo Scientific). All stable $^{2/1}H$ and $^{18/16}O$ isotope ratio measurements were expressed in d per mil unit (o/oo) versus the international reference materials Standard Mean Ocean Water and Standard Light Antarctic Precipitation (IAEA). Moreover, for each batch of urine analysis, a six-point water calibration curve was determined with known $^{2/1}H_2{}^{18/16}O$ enrichments. Calibrators and urine samples were then prepared for $^{2/1}H$ determination. After uncapping a 12-ml exetainer (Labco International), 5 mg of activated charcoal (Fisher Scientific) was introduced into the

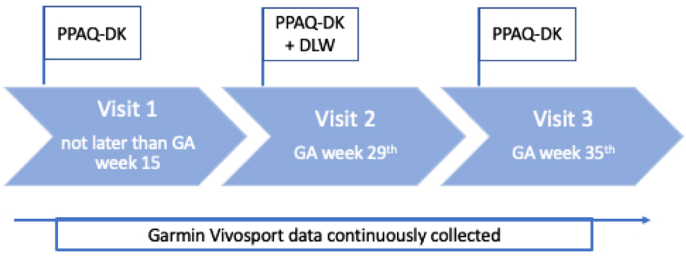


**Figure 1** — Methods used and time points of the data collection. DLW = doubly labeled water; PPAQ-DK = Danish pregnancy physical activity questionnaire; GA = gestational age.

exetainer followed by a platinum catalytic rod (Thermo Scientific). The activated charcoal was added to remove any potential contaminants in the urine sample that might poison the catalyst. After putting 0.2 ml of urine into the exetainer, the exetainer was recapped and placed into the GasBench II and flushed with 2% $H_2$ in helium (99.999% $H_2$ and 99.996% helium) for 7 min. The samples were equilibrated for at least 4 hr with the $H_2$ at room temperature. After equilibration, six aliquots of headspace were injected into the isotope ratio mass spectrometry for $^{2/1}H$ isotope ratio measurement against the reference $H_2O$ Vienna Standard Mean Ocean Water and Standard Light Antarctic Precipitation (VSMOV2). For $C^{18/16}O_2$ analysis, 0.2 ml of calibrators or urine was added to the 12-ml exetainer, and the exetainer was recapped and placed into the GasBench II and flushed with 0.9% $CO_2$ in helium (99.999% $CO_2$ and 99.996% helium) for 7 min. The samples were equilibrated for 24 hr with the $CO_2$ at room temperature after which six aliquots of the headspace were injected into the isotope ratio mass spectrometry for $^{18/16}O$ isotope ratio measurement against the reference $H_2O$ Standard Light Antarctic Precipitation 2 (SLAP2). No samples were lost during the analysis.

The slope-intercept protocol was used to calculate TEE (Bhutani, 2015). First, the enrichment estimate rates of $H_2$ and $^{18}O$ were calculated. Each sample data (enrichment estimate) were baseline corrected. Then, the dilution space for the two isotopes (oxygen [kO] and deuterium [kH]) was calculated by using the natural logarithm of the mean enrichment for both $H_2$ and $^{18}O$ with the number of days elapsed. The total body water was derived from the average dilution space of $H_2$ and $^{18}O$ and then divided by the factor for correction for in vivo isotopic exchange, which is 1.04 for $H_2$ and 1.01 for $^{18}O$. The ratio between $H_2$ and $^{18}O$ dilution spaces was (mean ± *SD*) 1.02 ± 0.05 (Bhutani, 2015). The rate of $CO_2$ production ($rCO_2$) was calculated as (total body water/2; kO—kH). Subsequently, TEE was calculated, using the modified Weir equation, as $22.4 (3.9 [rCO_2/\text{Food Quotient}] + 1.1 [rCO_2]) \times 4.184/1{,}000$, with the Food Quotient assumed to be 0.85 (Löf, 2011; Speakman et al., 2021). Basal metabolic rate was estimated from body weight, height, and age by an equation derived from the Harris–Benedict equation for pregnant women (Hronek et al., 2009). Finally, PAEE was determined by subtraction of the basal metabolic rate and the thermic effect of food (assumed to be 10% of TEE) from TEE (Hronek et al., 2009; Westerterp et al., 2013). PA level was calculated by dividing TEE by the basal metabolic rate (Löf, 2011).

## Activity Tracker

At Visit 1, participants were provided with a wrist-worn consumer activity tracker with a built-in heart rate monitor, known as photoplethysmography, and an accelerometer (Garmin Vivosport, Garmin International; Garmin International, n.d.) which had to be worn on the nondominant wrist 24/7 throughout pregnancy. The Garmin Vivosport is lightweight, has a battery life of up to 7 days, and can store activity and heart rate data for up to 14 days between synchronization (Garmin International, n.d.). The research team monitored compliance with wearing the tracker and syncing data through the Fitabase research platform (Fitabase). The participant was instructed on how to synchronize and charge the tracker regularly; an email reminder was sent if a participant was not syncing for more than 7 days. To be included in the data analysis, a valid day of measurement comprised at least 12 hr of daily wear time (from 6 a.m. to 12 a.m.) with at least four valid days (weekdays and/or weekend days) per week. Validation and inclusion of days and weeks were based on heart rate data which were sampled every 15 s by the activity tracker.

Activity estimates were based on Garmin's proprietary algorithms which were unavailable to the researchers. The participant's height, body weight, age, and sex were entered in the Garmin Connect app at inclusion; body weight was measured at Visits 2 and 3 and reentered into the app. Basal metabolic rate, PAEE, and moderate-to-vigorous intensity PA were derived directly from the activity tracker. Only PA with a metabolic equivalent of task value of ≥ 3 in bouts of at least 10 consecutive minutes was recorded as moderate-to-vigorous intensity PA by the tracker. We calculated TEE by adding PAEE, basal metabolic rate, and thermic effect of food which was assumed to be 10% of TEE (Hronek et al., 2009; Westerterp et al., 2013). The tracker categorized time into sedentary, active, or highly active. Total sedentary time was defined as little to no activity monitored, such as minimal movement, sitting, resting, or sleeping (Garmin International, n.d.). The activity tracker also obtained total sleep time, and we calculated sedentary awake time (i.e., SED) by subtracting sleep time from total sedentary time.

## Pregnancy PA Questionnaire

The PPAQ is a subjective instrument estimating PA in the current trimester (Chasan-Taber et al., 2004). Adapted from the international PA questionnaire (Craig et al., 2003), the PPAQ collects data on different activities, for example, household, occupational, and sports. The FitMum research group translated PPAQ into Danish (PPAQ-DK) and validated it in a Danish pregnant population (Krøner et al., 2020). The PPAQ-DK was electronically distributed to the participants immediately after Visits 1, 2, and 3. The PPAQ-DK has questions about time spent in sedentary activities ($n = 5$; Barone Gibbs et al., 2020), light-intensity activities ($n = 8$), moderate-intensity activities ($n = 15$), and vigorous-intensity activities ($n = 2$), as well as two open questions if some activities were not stated. PAEE was calculated as the number of minutes spent in each reported activity multiplied by its metabolic equivalence of task value (Cohen et al., 2013). To calculate moderate-to-vigorous intensity PA, minutes at moderate intensity and vigorous intensity were added.

## Comparisons of the Three Methods

DLW in a 14-day period after Visit 2 was used as a criterion method for TEE, PAEE, and PA level. For comparison, the averaged tracker variables during the same 14-day period and PPAQ-DK answered at Visit 2 were used. When comparing PAEE, moderate-to-vigorous intensity PA; SED from activity tracker data with PPAQ-DK at Visits 1, 2, and 3; and the tracker data were averaged from Visit 1 to randomization (six full days), from randomization to Visit 2, and from Visit 2 to Visit 3, respectively. Measurements from the activity tracker and PPAQ were used for comparison purposes.

## Statistics

All data were analyzed using R (version 4.0.4, 2021-02-15; R Core Team, [2020]). Descriptive statistics were presented as mean (*SD*) or median (interquartile range). Pearson correlation was used to assess the relationship between estimates of TEE, PAEE, and PA level, respectively, from the activity tracker and

DLW, and the relationship of PAEE from PPAQ-DK and DLW. Also, Pearson correlation was used to assess the relationship between PAEE, moderate-to-vigorous intensity PA, and SED estimates, respectively, from the activity tracker and PPAQ-DK at Visits 1, 2, and 3. The agreement between methods was based on the correlation coefficient ($r$) classified as weak (.10–.39), moderate (.40–.69), strong (.70–.89), or very strong (.90–1.00; Schober & Schwarte, 2018). Bland–Altman analysis (Bland & Altman, 1999) was used to explore the levels of agreement for TEE, PAEE, and PA levels, respectively, between the activity tracker and DLW and the agreement of PAEE between PPAQ-DK and DLW. Additionally, Bland–Altman analysis was used to assess the agreement of PAEE, moderate-to-vigorous intensity PA, and SED, respectively, between the activity tracker and PPAQ-DK at Visits 1, 2, and 3. In all the Bland–Altman plots, the means of the two methods were plotted on the $x$-axis against the difference in the $y$-axis, except for DLW as this was considered the criterion method and hence directly plotted in the $x$-axis (Hills et al., 2014). The mean absolute percentage error was calculated for the tracker and PPAQ compared to DLW (Argent et al., 2022; Johnston et al., 2021). Finally, linear regression analysis was performed to find a possible variation between the methods (i.e., proportional bias) presented as slope (95% confidence interval). The dependent and independent variables were the same as in the Bland–Altman plots. The significance level was set at 5%.

## Results

At enrollment, participants were 31.5 ± 4.3 years old, had a gestational age of 12.9 (9.4–13.9) weeks, a body weight of 75.4 ± 15.3 kg, and a median prepregnancy body mass index of 24.1 (21.8–28.7) kg/m$^2$. During the 6-day baseline period, participants wore the activity tracker for a total of 1,278 days out of 1,314 potential days (97%; 6 [3–6 days]). From randomization to delivery, participants wore the tracker for a total of 32,421 days out of 42,041 potential days (77%; 172 [4–230 days]). For the comparison of the activity tracker and DLW data, 134 participants were included, whereas 133 participants were included in the comparison of PPAQ-DK and DLW data. There were no significant differences in baseline characteristics (body weight, age, educational level, gestational age, and parity) for those who had DLW and those who did not. The number of participants included in the comparison of data from PPAQ-DK and activity trackers was 218 at Visit 1, 181 at Visit 2, and 165 at Visit 3.

### Validity of Activity Tracker and PPAQ-DK Against DLW

Summary statistics of the method comparisons are shown in Table 1. A moderate correlation was found between TEE from the activity tracker and DLW ($r = .63$; $p < .001$; Figure 2A). However, PAEE and PA levels from the activity tracker did not correlate with PAEE and PA levels from DLW (Figure 2B and 2C). Moreover, PAEE from PPAQ-DK did not correlate with PAEE from DLW (Figure 2D). The activity tracker overestimated TEE (mean bias: 503 kcal/day; Figure 3A), and the proportional bias was not significant (slope = –0.01; [–0.2 to 0.2]; $p = .919$; Table 1). Also, the activity tracker overestimated PAEE (mean bias: 303 kcal/day; Figure 3B) and PA level (mean bias: 0.2; Figure 3C) when compared with DLW. For PAEE around 400 kcal/day and PA level around 1.3, the activity tracker shifted gradually to underestimate values compared to DLW. The thermic effect of food is not always included in calculations of TEE and PAEE (Hallal et al., 2013), that is, TEE = BMR + PAEE + thermic effect of food or TEE = BMR + PAEE.

**Table 1 Summary Statistics of the Methods' Comparisons**

| Variable | Contrast | Time | n | Mean bias | 95% LOA | | Proportional bias, intercept (slope) | [95% CI] | *p* |
|---|---|---|---|---|---|---|---|---|---|
| Total energy expenditure (kcal/day) | Tracker vs. DLW | Visit 2 (29th GA week) | 134 | 503 | –133 | 1,139 | 477 (–0.01) | [–0.2, 0.2] | .919 |
| Physical activity energy expenditure (kcal/day) | | | 134 | 303 | –284 | 890 | 694 (–1) | [–1.4, –0.8] | <.000 |
| Physical activity level (TEE/BMR) | | | 134 | 0.2 | –0.2 | 0.5 | 1.6 (–1) | [–1.3, –0.8] | <.000 |
| Physical activity energy expenditure (kcal/day) | PPAQ-DK vs. DLW | | 133 | 1,513 | 308 | 2,718 | 1,786 (–0.8) | [–1.6, 0.2] | .050 |
| Physical activity energy expenditure (kcal/day) | Tracker vs. PPAQ-DK | Visit 1 (GA ≤ 15 weeks) | 218 | –1,286 | –2,565 | –6 | 390 (–1.5) | [–1.6, –1.4] | <.000 |
| | | Visit 2 (29th GA week) | 179 | –1,356 | –2,740 | 28 | 550 (–1.6) | [–1.7, –1.4] | <.000 |
| | | Visit 3 (35th GA week) | 160 | –1,046 | –2,570 | 478 | 670 (–1.4) | [–1.6, –1.3] | <.000 |
| Moderate-to-vigorous intensity physical activity (min/day) | Tracker vs. PPAQ-DK | Visit 1 (GA ≤ 15 weeks) | 218 | –90 | –230 | 50 | 5 (–1.9) | [–2, –1.8] | <.000 |
| | | Visit 2 (29th GA week) | 181 | –86 | –219 | 47 | 12 (–1.9) | [–2, –1.8] | <.000 |
| | | Visit 3 (35th GA week) | 165 | –72 | –222 | 78 | 11 (–1.8) | [–1.9, –1.7] | <.000 |
| Sedentary time (hr/day) | Tracker vs. PPAQ-DK | Visit 1 (GA ≤ 15 weeks) | 218 | 6.8 | 1.3 | 12.3 | 18 (–1.2) | [–1.4, –1.05] | <.000 |
| | | Visit 2 (29th GA week) | 181 | 7.2 | 2.2 | 12.2 | 21 (–1.5) | [–1.6, –1.3] | <.000 |
| | | Visit 3 (35th GA week) | 162 | 8.1 | 2.2 | 13.8 | 18 (–1.1) | [–1.4, –0.9] | <.000 |

*Note*. TEE = total energy expenditure; BMR = basic metabolic rate; DLW = doubly labeled water; PPAQ-DK = Danish pregnancy physical activity questionnaire; GA = gestational age; n = number; LOA = limit of agreement; CI = confidence interval.

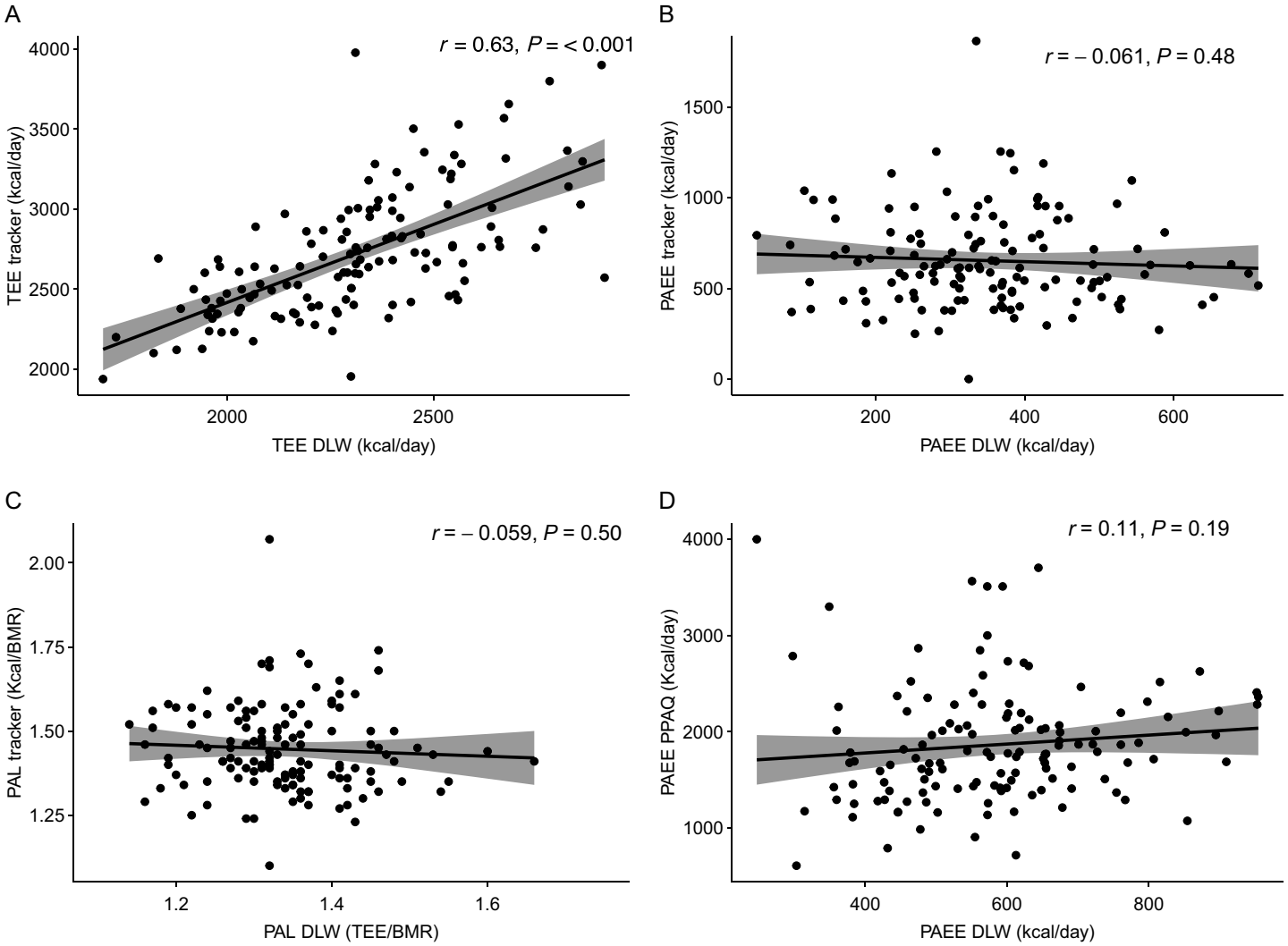


**Figure 2** — Correlations between the activity tracker and PPAQ-DK outcomes, respectively, and DLW outcomes. (A) TEE: activity tracker versus DLW; (B) PAEE: activity tracker versus DLW; (C) PAL: activity tracker versus DLW; and (D) PAEE: PPAQ-DK versus DLW. PPAQ-DK = Danish pregnancy physical activity questionnaire; TEE = total energy expenditure; DLW = doubly labeled water; PAEE = PA energy expenditure; PAL = PA level; BMR = basic metabolic rate.

Notably, when we omitted the thermic effect of food in our calculations, we saw a relatively good agreement for TEE (mean bias: 222 kcal/day) and PAEE (mean bias: 72 kcal/day), respectively, between the activity tracker and DLW. PPAQ-DK overestimated PAEE (mean bias: 1,513 kcal/day) compared with DLW (Figure 3D) with insignificant proportional bias (slope = –0.8; [–1.6 to 0.2]; $p = .050$; Table 1). When comparing data from the tracker and DLW, mean absolute percentage error was 18.6% (11.7%) for TEE, 143.0% (213.8%) for PAEE, and 11.8% (9.3%) for PA level. When comparing data from PPAQ and DLW, mean absolute percentage error was 241.0% (172.6%) for PAEE.

## Comparison Between Activity Tracker and PPAQ-DK

PAEE from the activity tracker and PPAQ-DK correlated weakly at Visits 1, 2, and 3 ($r$: .15–.22; Figure 4A–C). Moderate-to-vigorous intensity PA and SED from the activity tracker and PPAQ-DK correlated weakly ($r$: .15–.17; Figure 4F, G, and H) or not at all (Figures 4D, 4E, and 4I). The pattern of the comparisons between PAEE, moderate-to-vigorous intensity PA, and SED by the activity tracker and PPAQ-DK was consistent throughout the three visits (Figure 5, Table 1). The mean biases between PPAQ-DK and the activity tracker were −1,286, −1,356, and −1,046 kcal/day for PAEE (Figure 5A–C, Table 1); −90, −86, and −72 min/day for moderate-to-vigorous intensity PA (Figure 5D–F, Table 1); and 6.8, 7.2, and 8.1 hr/day for SED (Figure 5G–I, Table 1) at Visits 1, 2, and 3, respectively. The activity tracker consistently reported PAEE and moderate-to-vigorous intensity PA to be lower than reported by the PPAQ-DK. On the contrary, the activity tracker reported SED to be higher than reported by the PPAQ-DK. The linear regression analysis showed consistent and significant proportional biases ($p < .000$) between the activity tracker and PPAQ-DK for all variables and at all visits (Table 1).

# Discussion

This is the first study to validate a consumer activity tracker and PPAQ-DK against DLW in pregnant women. TEE from the

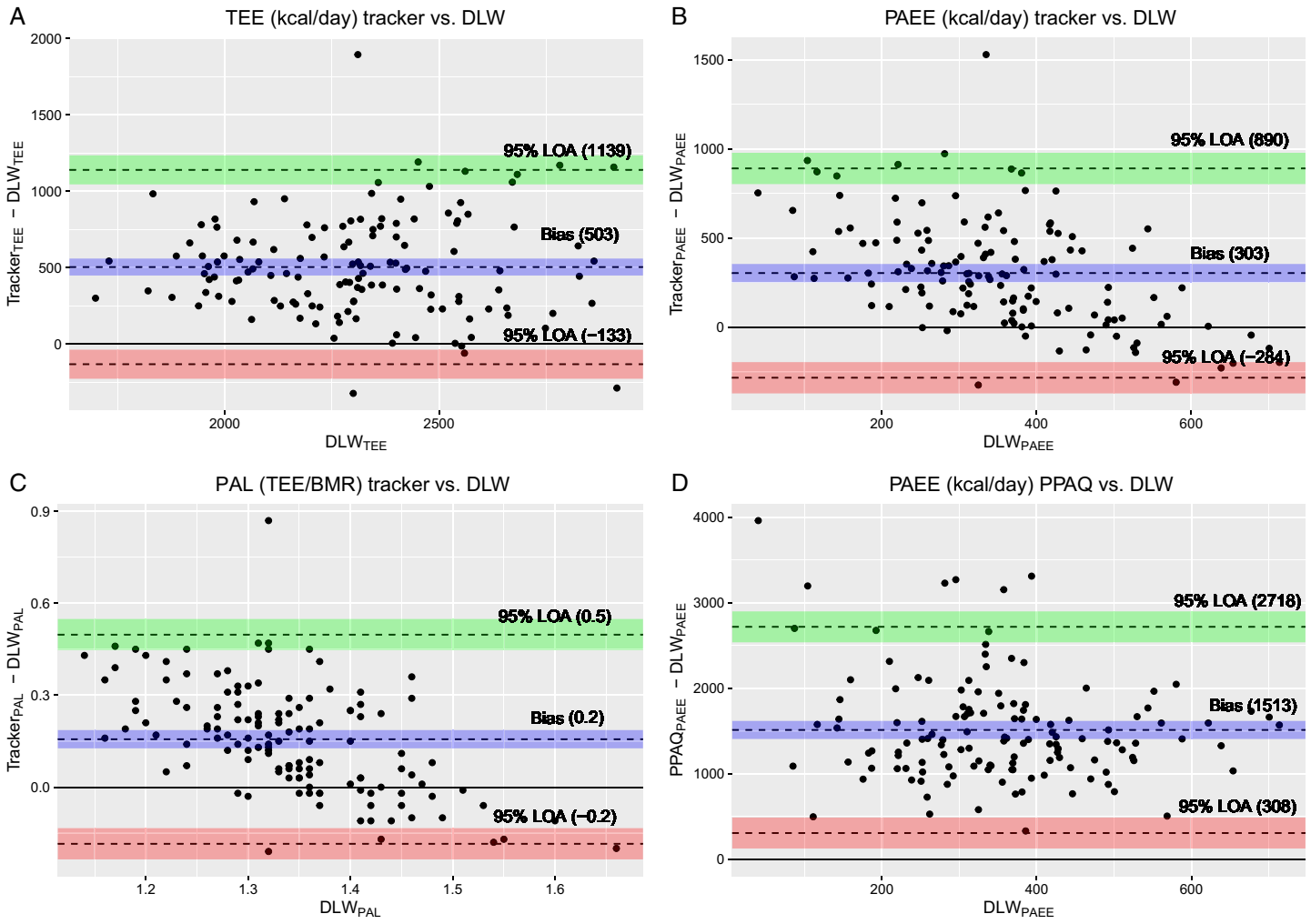


**Figure 3** — Bland–Altman plots for the activity tracker and PPAQ-DK outcomes, respectively, against DLW outcomes: (A) differences between activity tracker and DLW; (B) PAEE: differences between activity tracker and PPAQ-DK versus DLW; (C) PAL: differences between activity tracker and DLW; and (D) PAEE: differences between PPAQ-DK and DLW. PPAQ-DK = Danish pregnancy physical activity questionnaire; TEE = total energy expenditure; DLW = doubly labeled water; PAEE = PA energy expenditure; PAL = PA level; BMR = basic metabolic rate; LOA = limit of agreement.

activity tracker and DLW correlated moderately well, which might be due to the dominance of BMR in both estimates. Also, we found better agreement of PAEE estimates from the activity tracker than from PPAQ-DK when compared with DLW. Moreover, throughout our study, pregnancy tracker estimates of PA were lower and estimates of SED were higher than estimates from PPAQ-DK. Participants showed good compliance with wearing the activity tracker during the baseline period (97%) and throughout pregnancy (77%), which is comparable to another study among pregnant women (Grym et al., 2019).

A previous review of the validity of different Garmin activity trackers (Evenson & Spade, 2020) concluded that the error for determining energy expenditure generally was considerable compared to a criterion method (e.g., indirect calorimetry and triaxial accelerometer). However, that review did not include the Garmin Vivosport activity tracker used in the present study. Wahl et al. tested the validity of 11 different activity trackers during exercise in 20 healthy sports students, including three Garmin trackers (but not Vivosport) and used indirect calorimetry as the criterion method (Basset et al., 2017). Using an exercise protocol with different velocities, they found that the activity trackers generally overestimated energy expenditure when exercise velocity was low and underestimated energy expenditure when PA intensity increased (Basset et al., 2017). Murakami et al. tested the validity of 12 activity trackers, including Garmin Vivofit, in 19 healthy women and men (Murakami et al., 2016, 2019). Participants wore trackers during a standardized day in a metabolic chamber as well as during 15 free-living days where PAEE was also determined by DLW. They found that most of the trackers underestimated PAEE, and Garmin Vivofit underestimated PAEE during standardized (mean bias: −499.3 kcal/day) and free-living conditions (mean bias: −727.8 kcal/day). In comparison, we found that Garmin Vivosport overestimated PAEE compared to DLW. Two different Fitbit activity trackers have also been validated against DLW (Shook et al., 2022; Siddall et al., 2019). The Fitbit Surge tended to underestimate TEE (mean bias: −656 kcal/day) in 20 military personnel (Siddall et al., 2019), whereas the Fitbit Alta HR showed moderate to strong agreement and correlation of TEE compared to DLW with small degrees of overestimation during two 14-day assessment periods (means bias: 17 and 76 kcal/day) in 24 healthy adults (Shook et al., 2022). Possible reasons for conflicting results between studies are different hardware and software

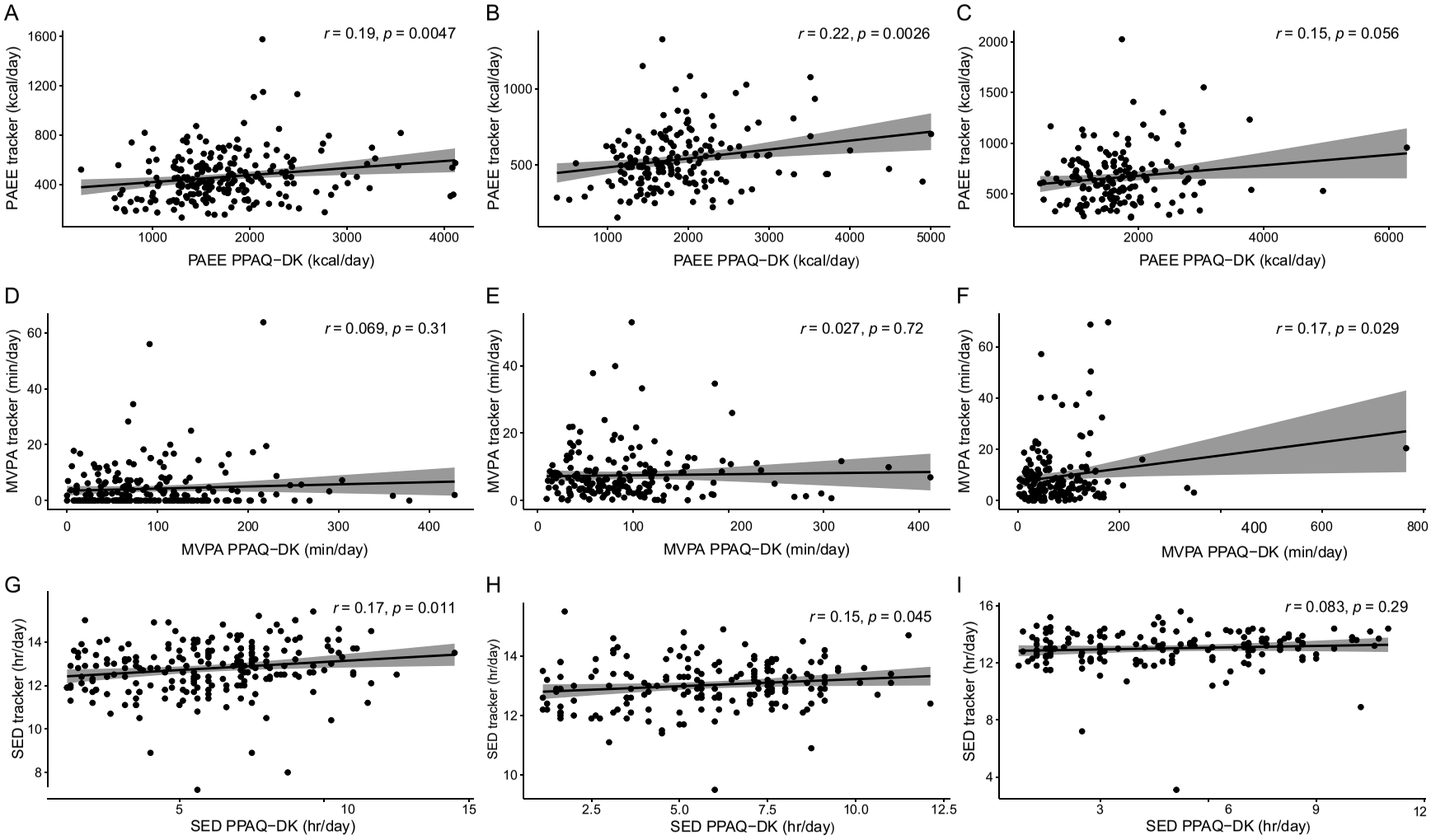


**Figure 4** — Correlations between activity tracker and PPAQ-DK outcomes. PAEE: activity tracker versus PPAQ-DK at Visits 1 (A), 2 (B), and 3 (C); MVPA: activity tracker versus PPAQ-DK at Visits 1 (D), 2 (E), and 3 (F); and SED: activity tracker versus PPAQ-DK at Visits 1 (G), 2 (H), and 3 (I). PPAQ-DK = Danish pregnancy physical activity questionnaire; PAEE = PA energy expenditure; MVPA = moderate-to-vigorous intensity PA; SED = sedentary time.

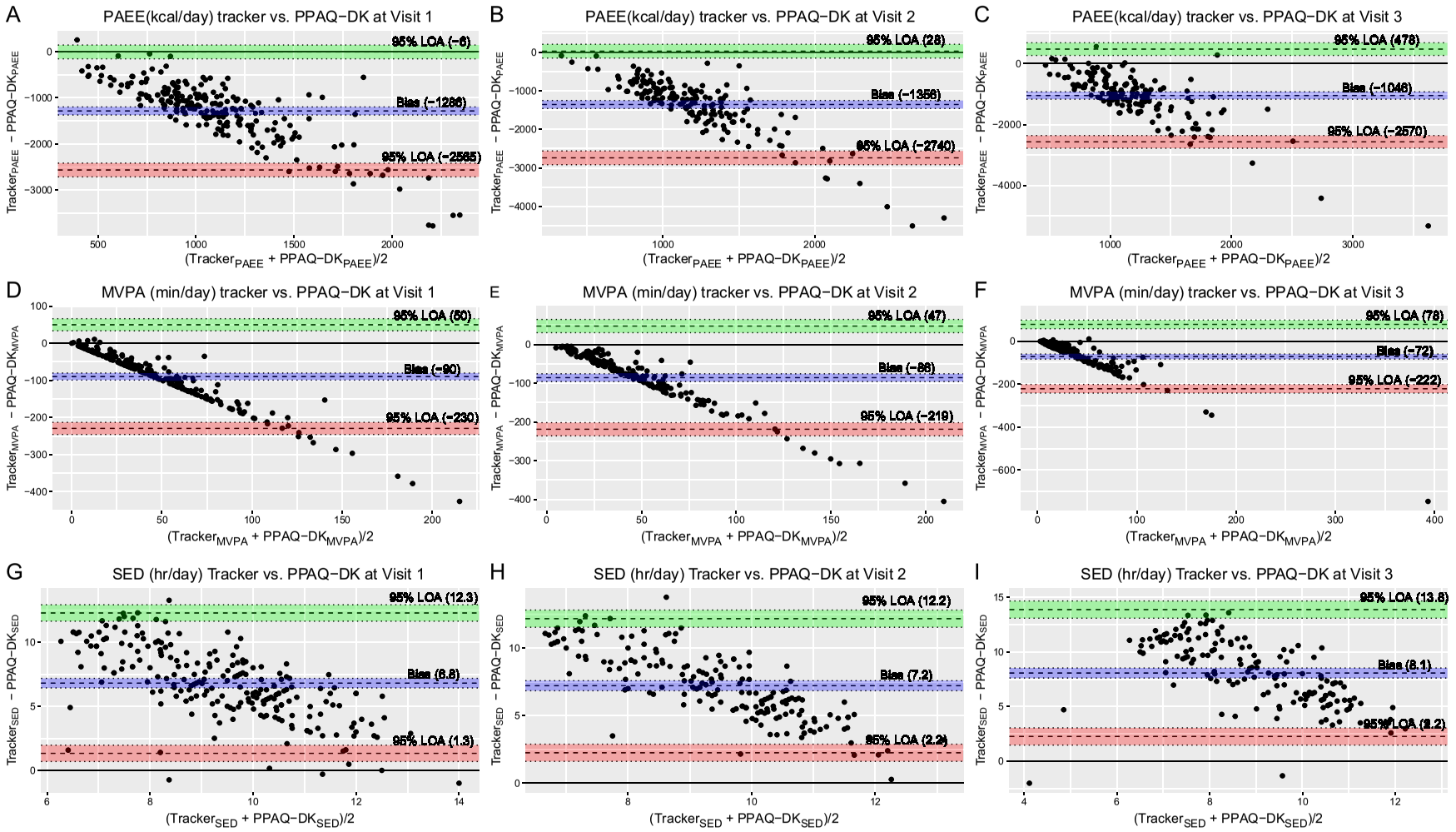


**Figure 5** — Bland–Altman plots for the activity tracker and PPAQ-DK outcomes: PAEE: differences between PPAQ-DK and activity tracker versus sums at Visits 1 (A), 2 (B), and 3 (C); MVPA: differences between PPAQ-DK and activity tracker versus sums at Visits 1 (D), 2 (E), and 3 (F); and SED: differences between PPAQ-DK and activity tracker versus sums at Visits 1 (G), 2 (H), and 3 (I). PPAQ-DK = Danish pregnancy physical activity questionnaire; PAEE = PA energy expenditure; MVPA = moderate-to-vigorous intensity PA; SED = sedentary time; LOA = limit of agreement.

in the multitude of commercial activity trackers on the market that are constantly updated (Henriksen et al., 2018; Woolley et al., 2019). Also, DLW is the gold standard for measuring free-living TEE, but the calculation of PAEE from DLW relies on several presumptions (Westerterp, 2017).

The PPAQ and PPAQ-DK have not previously been validated against DLW, but Besson et al. assessed the validity of the recent PA questionnaire against DLW in healthy adults (Besson et al., 2010). They found that the recent PA questionnaire underestimated PAEE which is in contrast to our findings for PPAQ-DK. Pedersen et al. tested another PA questionnaire, the PA Scale, against a combined accelerometer and heart rate monitor in Danish adults (Pedersen et al., 2018). They found that the PA Scale overestimated PAEE, which is similar to our findings. Brett et al. reported that PPAQ highly overestimated moderate-to-vigorous intensity PA when compared with the omniaxial Actical (Brett et al., 2015), which is in line with our results. Also, a systematic review of PA questionnaires for pregnant women found that the PPAQ validity was low in assessing moderate-to-vigorous intensity PA (Sattler et al., 2018). Similar to our findings, Barone Gibbs et al. found that PPAQ significantly underestimated SED when compared with both a thigh-worn activPAL3 micro (PAL Technologies Ltd.) (criterion method) and a waist-worn Actigraph GT3X (Barone Gibbs et al., 2020). Our findings affirmed that self-reported data tend to overestimate PA and underestimate SED (Chinapaw et al., 2009).

A strength of this study is the use of the DLW technique, the gold standard method for determining TEE under free-living conditions, in a high number of pregnant women. We are the first to validate both the activity tracker Garmin Vivosport and PPAQ-DK against DLW in pregnant women. A further strength is that the measurements from the activity tracker and PPAQ-DK were compared in all three trimesters of pregnancy. A limitation of the present study is that the activity estimates from the activity tracker were based on Garmin's proprietary algorithms which were unavailable to the researchers. Moreover, the Garmin Vivosport software was automatically updated throughout the study period, which probably influenced the assessment of the PA metrics from the tracker.

## Conclusions

PAEE estimates from the consumer activity tracker Garmin Vivosport were superior to estimates from PPAQ-DK when compared to DLW as the criterion method, but the absolute error of both the tracker and PPAQ-DK was significant. In addition, TEE from the tracker and DLW correlated moderately well. Moreover, PAEE and moderate-to-vigorous intensity PA measured by the activity tracker were lower throughout pregnancy and SED was higher than reported using PPAQ-DK. Thus, newer consumer activity trackers complement questionnaires to estimate energy expenditure, PA, and SED. In addition, activity trackers might motivate pregnant women to increase their PA levels.

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# Paper 3

Original Paper

# Effects of Structured Supervised Exercise Training or Motivational Counseling on Pregnant Women's Physical Activity Level: FitMum - 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 PA recommendations remains low among pregnant women.

**Objective:** The purpose of this study was to evaluate the effects of offering structured supervised exercise training (EXE) or motivational counseling on PA (MOT) during pregnancy on moderate-to-vigorous intensity physical activity (MVPA) level. Additionally, complementary measures of PA using the Pregnancy Physical Activity Questionnaire (PPAQ) and gold standard doubly labeled water (DLW) technique were investigated. The hypotheses were that both EXE and MOT would increase MVPA in pregnancy compared with standard care (CON) and that EXE would be more effective than MOT. In addition, the association between MVPA and the number of sessions attended was explored.

**Methods:** A randomized controlled trial included 220 healthy, inactive pregnant women with a median gestational age of 12.9 (IQR 9.4-13.9) weeks. A total of 219 women were randomized to CON (45/219), EXE (87/219), or MOT (87/219). The primary outcome was MVPA (minutes per week) from randomization to the 29th gestational week obtained by a wrist-worn commercial activity tracker (Vivosport, Garmin International). PA was measured by the activity tracker throughout pregnancy, PPAQ, and DLW. The primary outcome analysis was performed as an analysis of covariance model adjusting for baseline PA.

**Results:** The average MVPA (minutes per week) from randomization to the 29th gestational week was 33 (95% CI 18 to 47) in CON, 50 (95% CI 39 to 60) in EXE, and 40 (95% CI 30 to 51) in MOT. When adjusted for baseline MVPA, participants in EXE performed 20 (95% CI 4 to 36) minutes per week more MVPA than participants in CON ($P$=.02). MOT was not more effective than CON; EXE and MOT also did not differ. MVPA was positively associated with the number of exercise sessions attended in EXE from randomization to delivery ($P$=.04). Attendance was higher for online (due to COVID-19 restrictions) compared with physical exercise training ($P$=.03). Adverse events and serious adverse events did not differ between groups.

**Conclusions:** Offering EXE was more effective than CON to increase MVPA among pregnant women, whereas offering MOT was not. MVPA in the intervention groups did not reach the recommended level in pregnancy. Changing the intervention to online due to COVID-19 restrictions did not affect MVPA level but increased exercise participation.

**Trial Registration:** ClinicalTrials.gov NCT03679130; https://clinicaltrials.gov/ct2/show/NCT03679130

**International Registered Report Identifier (IRRID):** RR2-10.1136/bmjopen-2020-043671

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**KEYWORDS**

motivation; physical activity; pregnancy; pregnant; RCT; randomized controlled trial; intervention; commercial activity tracker; tracker; COVID-19; maternal health; doubly labeled water; physical activity questionnaire; women's health; maternal; maternity; digital health; exercise; fitness; health outcome

## 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, preeclampsia, cesarean delivery [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 the everyday life of pregnant women.

A diverse range of approaches to PA interventions exists, of which structured supervised exercise training and motivational counseling on PA 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 has also been shown to reduce the decline or even increase PA during pregnancy [13-15]. Structured supervised exercise and motivational counseling on PA have been applied separately in studies of pregnant women [16-26], 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 (DLW) technique [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

### Ethics Approval

The study was approved by the Danish National Committee on Health Research Ethics (H-18011067) and the Danish Data Protection Agency (P-2019-512) and registered at ClinicalTrials.gov (NCT03679130). The study adheres to the principles of the Helsinki declaration. Written informed consent was obtained at inclusion.

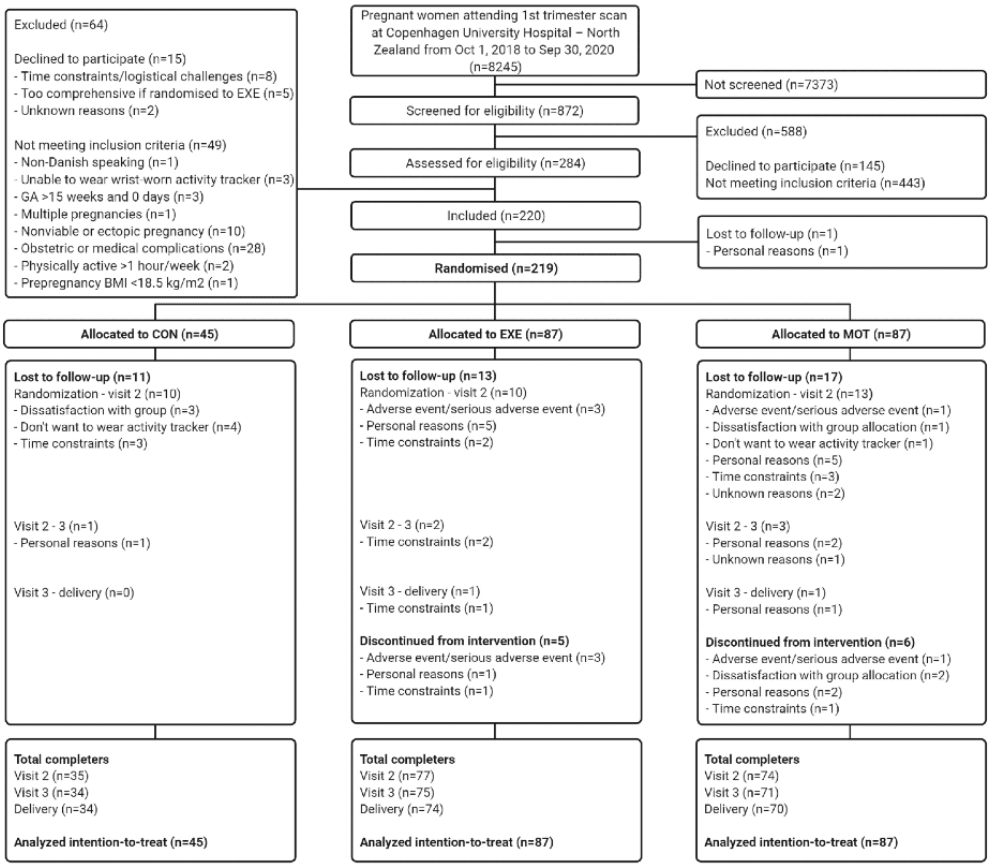
### Patient and Public Involvement

The development of FitMum was inspired by stakeholders: 27 semistructured 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 from 2018-2021 at the Department of Gynecology and Obstetrics at Copenhagen University Hospital–North Zealand, Denmark [32]. A total of 220 healthy, inactive pregnant women with gestational ages 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). Participants were invited to a test visit at the 29th gestational week (visit 2) and the 35th gestational week (visit 3).

**Figure 1.** Flowchart of the FitMum randomized controlled trial including enrollment, study group allocation, follow-up, and data analysis. GA: gestational age; CON: standard care; EXE: structured supervised exercise training; MOT: motivational counseling on physical activity.




## Interventions

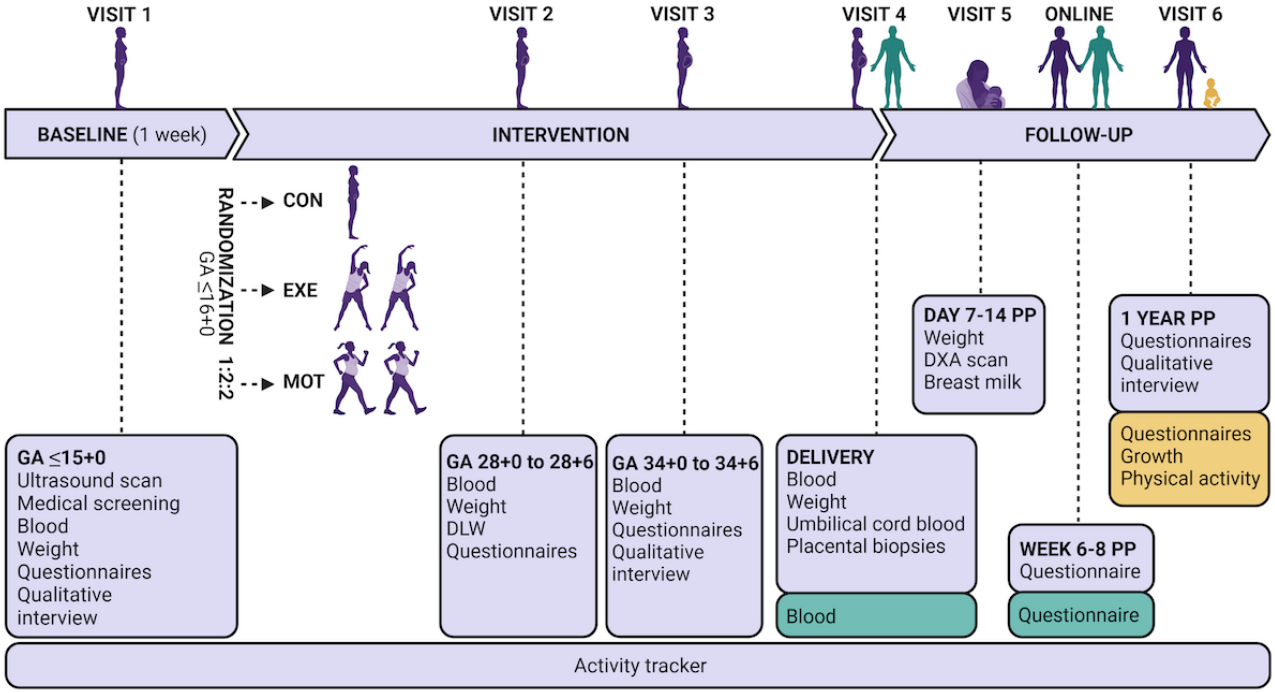
All 3 groups were offered standard maternal care. The EXE group was offered 1-hour group-based supervised exercise training at moderate intensity 3 times per week in a gym and swimming pool. The MOT group was offered 4 individual and 3 group PA motivational counseling face-to-face sessions of 1 to 2 hours duration during pregnancy and 1 weekly, personalized text message to support PA. The motivation technique applied is inspired by motivational interviewing [34], self-determination theory [35], and behavior change techniques [36].

Interventions ran from randomization until delivery. The target PA level for the EXE and MOT groups was at least 30 minutes per day at a moderate intensity as recommended in Denmark to healthy pregnant women [37]. Interventions were converted into online versions during the COVID-19 pandemic restrictions introduced in Denmark on March 11, 2020, and throughout the study period. The EXE group could access the swimming pool for 3 months during this period.

## Outcome Measures

The data collection procedures are illustrated in Figure 2. PA was continuously monitored by the activity tracker from randomization to delivery, by PPAQ at visits 1, 2, and 3, and by DLW at visit 2.

**Figure 2.** Schedule of visits. GA: gestational age; CON: standard care; EXE: structured supervised exercise training; MOT: motivational counseling on physical activity; DLW: doubly labeled water technique; PP: postpartum; DXA: dual-energy x-ray absorptiometry.




## Activity Tracker

The primary outcome was MVPA (minutes per week) from randomization to visit 2. PA was from inclusion to delivery continuously captured by a wrist-worn commercial activity tracker (Vivosport, Garmin International) [38] with a built-in heart rate monitor and accelerometer. Baseline PA was captured from inclusion to randomization (6 full days). PA with a metabolic equivalent of task (MET) value of ≥3 in bouts of at least 10 consecutive minutes was recorded automatically as MVPA by the activity tracker [38]. Secondary outcomes measured by the activity tracker were PA duration at moderate and vigorous intensities; 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 preset with PA notifications turned off and an identical face of the tracker showing only clock and battery level. After randomization, women in the MOT group were encouraged to personalize the tracker with, for example, individual goal settings and PA notifications as part of the intervention. Interaction with the tracker was neither encouraged nor controlled for the EXE and CON groups. Throughout the study period tracker software was automatically updated [38].

## Danish Version of the PPAQ

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

## DLW Technique

Participants collected 2 baseline urine samples prior to visit 2, drank the DLW dose at the visit, and then collected and stored 5 postdose urine samples at home on days 1, 4, 7, 11, and 14 and later at −80°C. [31,39]. The calculation of total energy expenditure (TEE) was based on the Weir equation [39], and the active energy expenditure (AEE) was calculated by subtracting the basal metabolic rate (BMR) from the TEE. BMR was estimated by an equation appropriate for pregnant women [40]. 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) [38] 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 R software (R Foundation for Statistical Computing).

## Statistical Analyses

Statistical analyses were performed according to the statistical analysis plan, which includes a sample size calculation [33] using R. Data are presented as means and standard deviations for symmetric distributions, medians and IQRs for skewed data, and frequencies and percentages for categorical variables. The level of statistical significance was 5% except for the primary hypothesis which consisted of 2 subhypotheses; the type I error for each hypothesis test was a priori set to 2.5% to obtain a family-wise error rate of 5%. Wald-based 95% 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 nonwear time were imputed by multiple imputations in 25 data sets using a prespecified seed, preselected baseline variables (body weight, age, PA, educational level, and parity), and the random forest imputation model from the mice R package [41]. A statistician blinded for the intervention performed the imputation and the primary outcome analysis as an analysis of covariance 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 [42]. For the PPAQ-DK outcome, a constrained linear mixed model was fitted with the observation times as a factor [43]. Both within and between-group effects were reported as estimated differences in means. For the DLW outcome, a one-way analysis of variance was used to compare the 3 group averages. For the DLW outcome, a 1-way analysis of variance was used to compare the 3 group averages. Linear regression was used to model the relationship between attended intervention sessions and attained MVPA in the EXE and MOT groups.

# 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 (45/219), EXE (87/219) or MOT (87/219; Figure 1). Maternal baseline characteristics are presented in Table 1.

From randomization to visit 2, 15.1% (33/219) of participants were lost to follow-up (CON: 10/45, 22%; EXE: 10/87, 11%; MOT: 13/87, 15%). The main reason (18/33, 55%) was personal matters (eg, time consumed with participation or family reasons). From randomization to delivery, 18.7% (41/219) of 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 to 1.6) exercise sessions per week from randomization to visit 2, and 1.3 (95% CI 1.1 to 1.5) exercise sessions per week from randomization to delivery. Participants randomized to the MOT group joined 5.2 (95% CI 4.7 to 5.7) counseling sessions during their pregnancy.

**Table 1.** Baseline characteristics of randomized participants.

| Characteristics | All (n=219) | CON[a] (n=45) | EXE[b] (n=87) | MOT[c] (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[d] ($kg/m^2$), 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 (37.4) | 16 (3.56) | 40 (46.0) | 26 (29.9) |
| **Educational level, n (%)** | | | | |
| School ≥12 years | 191 (87.2) | 41 (91.1) | 74 (85.1) | 76 (87.4) |
| Further education ≥3 years | 175 (79.9) | 33 (73.3) | 73 (83.9) | 69 (79.3) |
| Employed/studying | 199 (90.9) | 39 (86.7) | 83 (95.4) | 77 (88.5) |

[a]CON: standard care.

[b]EXE: structured supervised exercise training.

[c]MOT: motivational counseling on physical activity.

[d]Prepregnancy BMI is calculated based on n=218 (CON: 45/218, EXE: 86/218, MOT: 87/218) due to a missing value.

## PA by Activity Tracker

### *Moderate-to-Vigorous Intensity Physical Activity*

The average MVPA (minutes per week) from randomization to visit 2 was 33 (95% CI 18 to 47) in CON, 50 (95% CI 39 to 60) in EXE, and 40 (95% CI 30 to 51) in MOT (Figure 3). When adjusted for baseline MVPA, participants in EXE performed 20 (95% CI 4 to 36) minutes per week more MVPA than participants in CON (*P*=.02; Multimedia Appendix 1).

The same pattern was seen throughout the entire pregnancy, hence the unadjusted average MVPA (minutes per week) was 35 (95% CI 19 to 51) in CON, 54 (95% CI 42 to 65) in EXE and 43 (95% CI 32 to 55) in MOT from randomization to delivery (Figure 3). Throughout pregnancy, participants in EXE performed 21 (95% CI 3 to 39) minutes per week more MVPA than participants in CON when adjusted for baseline MVPA (*P*=.02; Multimedia Appendix 1).

There were no significant differences in adjusted MVPA between CON and MOT (randomization to visit 2: *P*=.23; randomization to delivery: *P*=.27) or between MOT and EXE (randomization to visit 2: *P*=.14; randomization to delivery: *P*=.15; Multimedia Appendix 1).

Unplanned analysis on cumulative MVPA from randomization to delivery revealed great variability and that EXE tended to have more MVPA compared with MOT, which became significant in the late part of pregnancy (Figures 4 and 5). The same tendency was seen between CON and EXE, but the difference was insignificant. Cumulative MVPA did not differ between CON and MOT.

The number of training sessions attended in EXE from randomization to delivery was positively associated with MVPA level ($P$=.04). No association was present between the number of sessions attended in MOT and MVPA ($P$=.14).

**Figure 3.** Moderate-to-vigorous intensity physical activity (primary outcome) and additional activity tracker outcomes (mean and 95% CI) from randomization to visit 2 (29th week of gestation; solid line) and from randomization to delivery (dotted line). MVPA: moderate-to-vigorous intensity physical activity; CON: standard care; EXE: structured supervised exercise training; MOT: motivational counseling on physical activity.

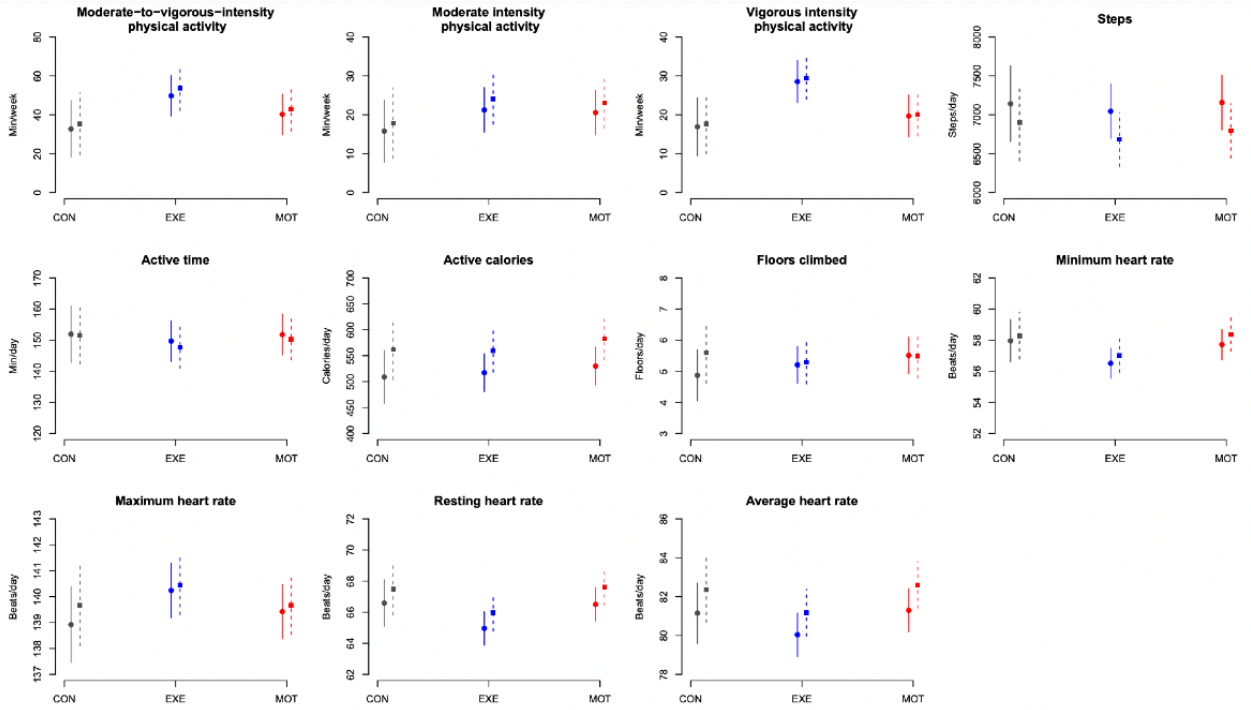



**Figure 4.** Cumulative moderate-to-vigorous intensity physical activity from randomization to delivery: (A) group averages, (B) EXE vs CON, (C) MOT vs CON, and (D) EXE vs MOT. MVPA: moderate-to-vigorous intensity physical activity; CON: standard care; EXE: structured supervised exercise training; MOT: motivational counseling on physical activity.

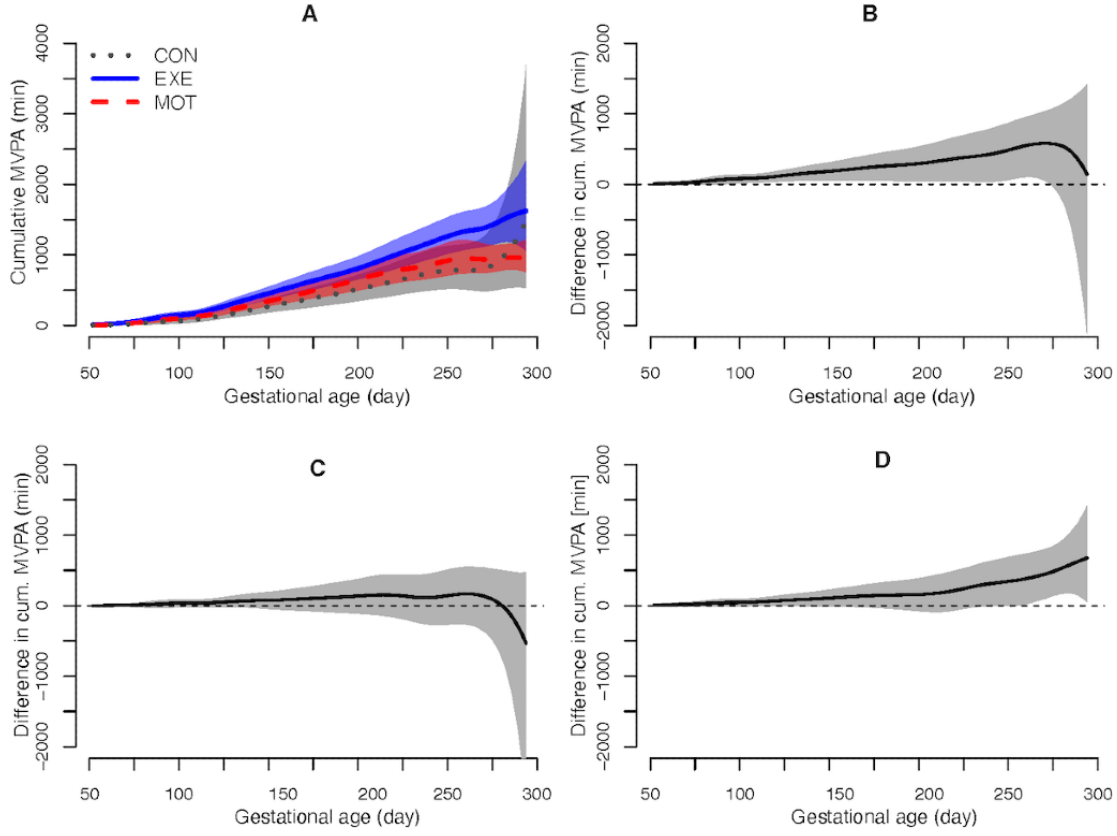
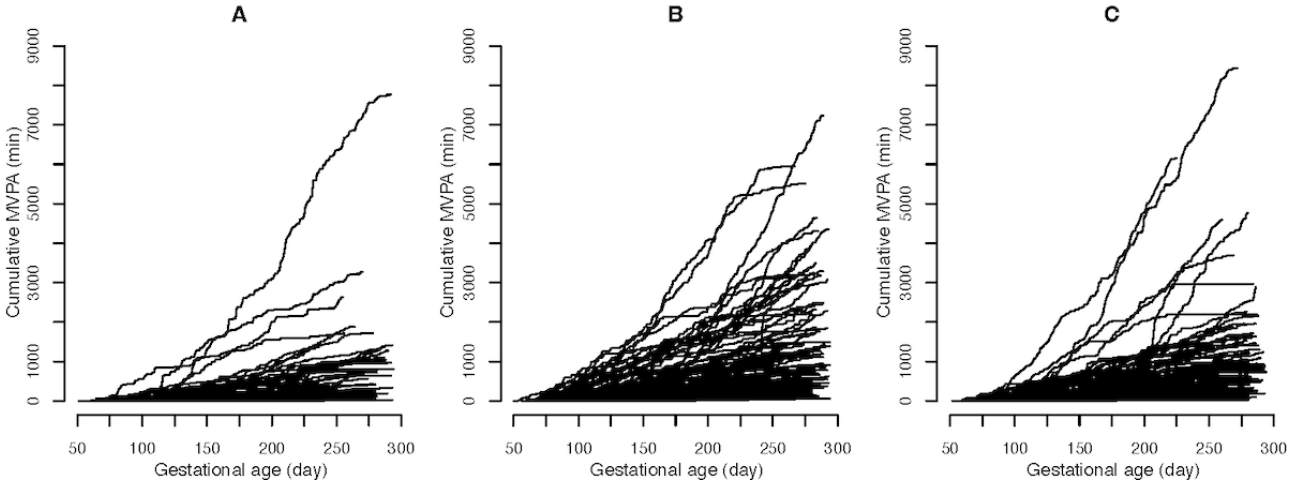


**Figure 5.** Individual cumulative moderate-to-vigorous intensity physical activity from randomization to delivery in (A) standard care, (B) structured supervised exercise training, and (C) motivational counseling on physical activity. MVPA: moderate-to-vigorous intensity physical activity.




### *COVID-19 Sensitivity Analysis*

MVPA (minutes per week) did not differ between participants included before the COVID-19 pandemic (physical intervention only, 120/219) and during the COVID-19 pandemic (online intervention only, 63/219) in either CON (–14, 95% CI –49 to 22; *P*=.44), EXE (–16, 95% CI –42 to 11; *P*=.25), or MOT (–6, 95% CI –37 to 25; *P*=.712; Multimedia Appendix 2).

Women in EXE offered the online intervention only participated in more exercise sessions per week than women offered the physical intervention only (online: 1.6, 95% CI 1.3 to 2.0 and physical: 1.1, 95% CI 0.9 to 1.4; *P*=.03). Participants in EXE attended on average 4.9 swimming pool sessions during 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, 95% CI 4.6 to 6.0 and online: 5.6, 95% CI 4.8 to 6.4; *P*=.97). Participants included before the COVID-19 pandemic and delivered during (36/219) were excluded in this analysis based on their mixed intervention.

## Secondary Activity Tracker Outcomes

All tracker outcomes are presented in Figure 3 and accompanying statistics in Multimedia Appendix 1. PA at a vigorous intensity (minutes per week) was higher in EXE than in both CON and MOT (CON vs EXE: randomization to visit 2: 13, 95% CI 4 to 22; randomization to delivery: 13, 95% CI 4 to 22; MOT vs EXE: randomization to visit 2: 9, 95% CI 1 to 16, randomization to delivery: 9, 95% CI 1 to 17). In addition, the maximum heart rate was 2 (95% CI 0.3 to 3) beats per minute higher in EXE compared with CON from randomization to visit 2. No other tracker outcomes differed between groups.

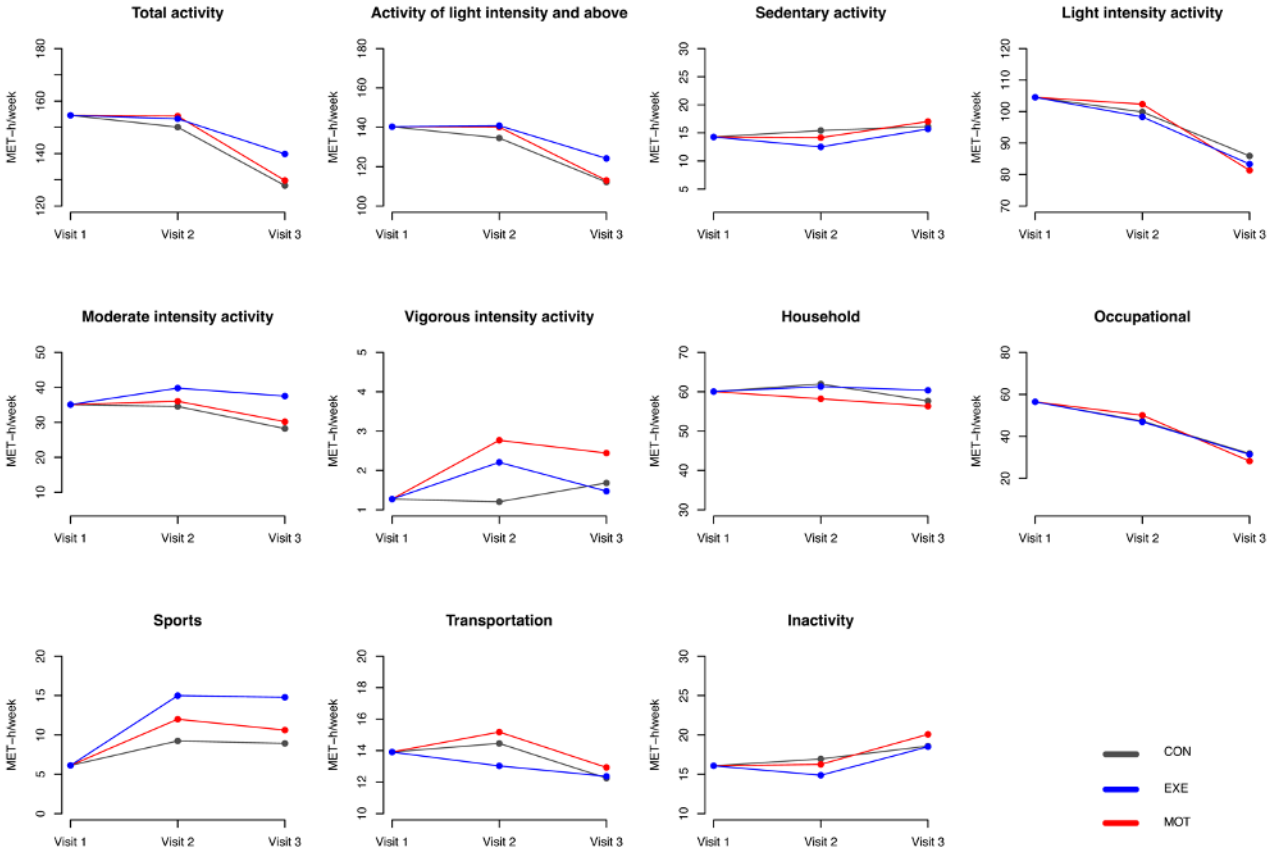
## PA by PPAQ-DK

PPAQ-DK was completed for visits 1, 2, and 3 by 100% (219/219), 83.1% (182/219), and 77.2% (169/219) participants, respectively. Figure 6 shows the PA behaviors categorized by intensity and type. Differences between and within groups are shown in Multimedia Appendix 3 and Multimedia Appendix 4.

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 groups (Multimedia Appendix 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 1 to visit 3 (Multimedia Appendix 4). When combined (MVPA), the activity level (MET hours per week) did not change through pregnancy in any of the groups (CON: visit 1-2: –1, *P*=.90; visit 1-3: –4, *P*=.36; EXE: visit 1-2: 4, *P*=.10; visit 1-3: 1, *P*=.61; MOT: visit 1-2: 2, *P*=.40; visit 1-3: –5, *P*=.37; data not shown).

The MET hours per week spent at sports activities increased significantly from visit 1 to visit 2 and visit 1 to visit 3 for both EXE and MOT, while no changes were observed in CON (Multimedia Appendix 4). A comparison between groups revealed that sports was significantly higher in EXE compared with CON and MOT at both visit 2 and visit 3 (Multimedia Appendix 3).

**Figure 6.** Baseline-constrained comparison between groups based on the means of physical activity level from the Danish version of the Pregnancy Physical Activity Questionnaire. MET: metabolic equivalent of task; CON: standard care; EXE: structured supervised exercise training; MOT: motivational counseling on physical activity.




### PA by DLW

A total of 134 participants (CON: 24/45, EXE: 53/87, MOT: 57/87) completed the DLW test and were included in the analysis. TEE (*P*=.14), AEE (*P*=.38), and PAL (*P*=.66) did not differ between groups (TEE [kcal per day]: CON 2215 [SD 238], EXE 2330 [SD 264], MOT 2331 [SD 260]; AEE [kcal per day]: CON 543 [SD 106], EXE 592 [SD 160], MOT 587 [SD 155]; and PAL [TEE/BMR]: CON 1.33 [SD 0.06], EXE 1.35 [SD 0.11], MOT 1.34 [SD 0.09]; Multimedia Appendix 5).

### Adverse Events and Serious Adverse Events

Adverse events and serious adverse events from inclusion to delivery among all participants did not differ between groups (Multimedia Appendices 6-8).

## Discussion

### Principal Findings

FitMum aimed to investigate the effects of offering EXE or MOT to generate evidence about how to implement PA in healthy pregnant women's lives. We hypothesized that both EXE and MOT would increase MVPA in pregnancy compared with 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 did not differ. The number of adverse events and serious adverse events did not differ between groups.

### Effectiveness of PA Interventions On PA Level In Pregnant Women

Several previous RCTs 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 [13,24,26,44,45]. Seneviratne et al [24] conducted a 16-week stationary biking program in overweight and obese pregnant women and reported improved aerobic fitness compared to controls. When determining PA objectively by accelerometry, Hayman et al [26] found an immediate increase in MVPA after 4 weeks of tailored PA advice and access to a resource library. On the contrary, no increase in PA as determined by accelerometry was found after a combined aerobic and strength exercise program [44], face-to-face individual PA consultations [13], or app-based PA behavior change techniques [45].

Women in EXE were encouraged to participate in 3 hours of EXE per week, but the participants attended on average less than half of the sessions, and throughout their pregnancy, the MVPA level was only a third (54 of 150 minutes per week) of the internationally recommended amount [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 with 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 [46,47]. MOT had a high intervention attendance, but even though MOT contained face-to-face counseling, text messaging, activity tracker use, and behavior change techniques as recommended [13,48,49], we found no effect on MVPA compared with CON. The processes behind this finding are currently being assessed via mixed methods. The cumulative MVPA in EXE was significantly higher compared with 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 with those who received the physical intervention.

### Methodologies Used to Determine PA

Combining 3 different methodologies to assess PA using objective (activity tracker and DLW) and subjective (PPAQ-DK) methods provides insight into the complexity of PA. 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. The PPAQ is considered one of the most valid and reliable questionnaires for the assessment of PA in pregnant women [27,50], but the inherent bias of self-reported PA is inevitable. The administration of the PPAQ-DK may have led to a heightened awareness of activity among participants [50], especially for members of the MOT group, 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 [39,51], 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 to 100 kcal per day higher in EXE and MOT compared with CON. On the other hand, active kilocalories recorded by the tracker and total activity obtained from the PPAQ-DK, which are equivalent to AEE from DLW, did not differ between groups. Therefore, the total activity probably did not differ between groups.

### Strengths and Limitations

FitMum is the first RCT to compare the effectiveness of 2 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 [49,52], but it might also not capture all activities. Notably, by default the tracker only reported activities with a MET value of ≥3 in bouts of at least 10 consecutive minutes as MVPA [38], and this might partly explain the relatively low MVPA in this study. An additional limitation was the impact of COVID-19 and the need to convert the physical interventions into online ones.

### Conclusions

Findings from this RCT demonstrate that offering EXE is more effective than CON to implement MVPA in healthy pregnant women's lives. Offering MOT was not more effective than CON; EXE and MOT also did not differ. The MVPA in the intervention groups did not reach the recommended PA level in pregnancy. Changing the intervention to online due to COVID-19 restrictions did not affect MVPA level but increased exercise participation. Based on the most effective intervention on MVPA during pregnancy (EXE) and the increased level of EXE sessions attended in the online setup during the COVID-19 pandemic, it might be beneficial to add home-based, online exercise sessions in future prenatal PA interventions.

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## Authors' Contributions

BS initiated and directed FitMum. SdPK, CBR, JMB, TDC, SM, SAA, EL, and BS developed the study protocol. SdPK, CBR, ADJ, and IH conducted intervention activities and collected data assisted by SAA, research assistants, and master students. EL was the clinical trial manager and supervised the clinical part of FitMum in collaboration with JMB, TDC, SM, and BS. AKJ performed and supervised statistical analyses. SAA performed the activity tracker data management, and JEL contributed with expertise on self-tracking. GvH performed the doubly labeled water analysis. SdPK and SAA contributed equally, analyzed data, and wrote the manuscript. All authors read, contributed to, and approved the final version of the manuscript.

## Conflicts of Interest

None declared.

## Multimedia Appendix 1

Comparison between groups based on imputed activity tracker datasets (intention-to-treat analysis) from randomization to visit 2 and delivery, respectively.
[DOCX File , 20 KB-Multimedia Appendix 1]

## Multimedia Appendix 2

Moderate-to-vigorous intensity physical activity before and during the COVID-19 pandemic.
[PNG File , 59 KB-Multimedia Appendix 2]

## Multimedia Appendix 3

Pregnancy Physical Activity Questionnaire outcome differences.
[DOCX File , 19 KB-Multimedia Appendix 3]

## Multimedia Appendix 4

Pregnancy Physical Activity Questionnaire outcome descriptive statistics.
[DOCX File , 19 KB-Multimedia Appendix 4]

## Multimedia Appendix 5

One-way analysis of variance test of the doubly labeled water outcomes.
[PNG File , 128 KB-Multimedia Appendix 5]

## Multimedia Appendix 6

Summary of adverse events and serious adverse events.
[XLSX File (Microsoft Excel File), 9 KB-Multimedia Appendix 6]

## Multimedia Appendix 7

All adverse events.
[XLSX File (Microsoft Excel File), 12 KB-Multimedia Appendix 7]

## Multimedia Appendix 8

All serious adverse events.
[XLSX File (Microsoft Excel File), 10 KB-Multimedia Appendix 8]

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## Abbreviations

**AEE:** active energy expenditure
**BMR:** basal metabolic rate
**CON:** standard care
**DLW:** doubly labeled water
**EXE:** structured supervised exercise training
**MET:** metabolic equivalent of task
**MOT:** motivational counseling
**MVPA:** moderate-to-vigorous intensity physical activity
**PA:** physical activity
**PAL:** physical activity level
**PPAQ-DK:** Danish Pregnancy Physical Activity Questionnaire
**RCT:** randomized controlled trial
**TEE:** total energy expenditure

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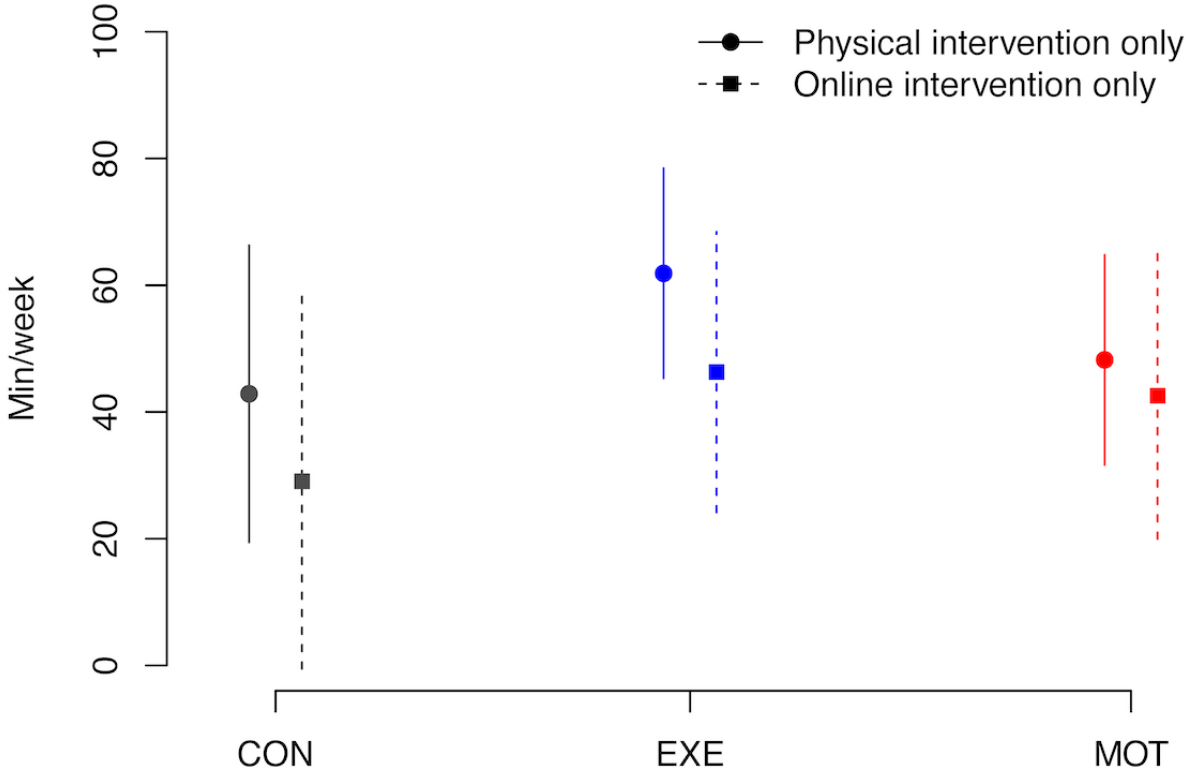
Multimedia Appendix 1. Comparison between groups based on imputed activity tracker datasets (intention-to-treat analysis) from randomization to visit 2 and delivery, respectively.

| | 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] | .02 | 21 [3;39] | .02 | 10 [-6;26] | .23 | 10 [-8;28] | .27 | 10 [-3;24] | .14 | 11 [-4;26] | .15 |
| **Moderate intensity (min/week)** | 5 [-3;13] | .22 | 6 [-4;16] | .23 | 3 [-5;11] | .45 | 4 [-6;13] | .47 | 2 [-5;9] | .57 | 2 [-6;10] | .58 |
| **Vigorous intensity (min/week)** | 13 [4;22] | .007 | 13 [3;22] | .009 | 4 [-5;13] | .39 | 3 [-6;13] | .47 | 9 [1;16] | .02 | 9 [1;17] | .02 |
| **Steps (steps/day)** | 251 [-173;674] | .24 | 136 [-274;546] | .51 | 149 [-272;571] | .49 | 32 [-375;440] | .88 | 102 [-246;449] | .57 | 104 [-233;441] | .54 |
| **Active time (min/day)** | 4 [-4;12] | .30 | 3 [-5;10] | .50 | 4 [-4;12] | .36 | 3 [-5;11] | .48 | 0.5 [-6;7] | .89 | 0.1 [-6;6] | .98 |
| **Active kilocalories (kcal/day)** | 25 [-15;64] | .22 | 15 [-32;62] | .52 | 29 [-10;69] | .15 | 30 [-17;77] | .20 | -5 [-37;28] | .78 | -15 [-53;24] | .44 |
| **Floors climbed (floors/day)** | 1 [-0.2;1] | .16 | -0.1 [-1;1] | .84 | 1 [-0.1;1] | .07 | -0.1 [-1;1] | .91 | -0.2 [-1;0.5] | .62 | -0.04 [-1;1] | .92 |
| **Minimum heart rate (beats/min)** | -0.5 [-1;1] | .26 | -0.3 [-1;1] | .62 | 0.1 [-1;1] | .86 | -0.4 [-1;1] | .42 | -1 [-1;0.1] | .12 | -1 [-2;0.1] | .11 |
| **Maximum heart rate (beats/min)** | 2 [0.3;3] | .02 | 1 [-0.4;3] | .14 | 1 [-1;2] | .27 | 0.3 [-1;2] | .68 | 1 [0;2] | .14 | 1 [-0.4;2] | .20 |
| **Resting heart rate (beats/min)** | -0.2 [-1;1] | .63 | -0.02 [-1;1] | .97 | 0.3 [-1;1] | .52 | 1 [-0.5;2] | .28 | -1 [-1;0.2] | .17 | -1 [-1;0.3] | .18 |
| **Average heart rate (beats/min)** | 0.03 [-1;1] | .94 | 0.02 [-1;1] | .97 | 0.5 [-0.4;1] | .26 | 1 [0.4;2] | .22 | -0.5 [-1;0.3] | .20 | -1 [-1;0.2] | .15 |

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 29$^{th}$ gestational week.*Significant difference. CI, confidence interval; CON, standard care; EXE, structured supervised exercise training; MOT, motivational counseling on physical activity.

Multimedia Appendix 2



Multimedia Appendix 3. Pregnancy Physical Activity Questionnaire outcome differences. Comparison between groups based on physical activity level from the Danish version of the Pregnancy Physical Activity Questionnaire (PPAQ-DK).

| | **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] | .70 | 12 [-8;32] | .23 | 4 [-12;20] | .61 | 2 [-18;22] | .85 | -1 [-14;12] | .88 | 10 [-6;26] | .21 |
| **Activity of ≥ light intensity** | 6 [-10;23] | .45 | 12 [-7;31] | .23 | 6 [-11;22] | .51 | 1 [-19;21] | .94 | 1 [-13;14] | .92 | 11 [-4;27] | .16 |
| **Intensity (MET-h/week)** | | | | | | | | | | | | |
| **Sedentary** | -3 [-6;1] | .10 | -0.4 [-5;4] | .84 | -1 [-5;2] | .47 | 2 [-3;5] | .68 | -2 [-4;1] | .24 | -1 [-5;2] | .44 |
| **Light** | -2 [-13;10] | .80 | 6 [-17;12] | .23 | 2 [-9;14] | .69 | 6 [-19;10] | .54 | -4 [-14;6] | .41 | 2 [-10;13] | .74 |
| **Moderate** | 5 [-4;14] | .26 | 9 [-2;21] | .11 | 1 [-8;11] | .75 | 2 [-10;13] | .74 | 4 [-4;11] | .31 | 7 [-2;16] | .11 |
| **Vigorous** | 1 [-1;3] | .23 | -0.2 [-2;2] | .82 | 2 [0;3] | .66 | 1 [-1;3] | .41 | -1 [-2;1] | .41 | -1 [-2;0.4] | .18 |
| **Type (MET-h/week)** | | | | | | | | | | | | |
| **Household** | -1 [-10;9] | .89 | 3 [-9;14] | .65 | -4 [-13;6] | .43 | -1 [-13;11] | .83 | 3 [-4;11] | .42 | 4 [-5;13] | .40 |
| **Occupational** | -0.4 [-13;12] | .96 | -0.4 [-15;15] | .96 | 3 [-10;15] | .66 | -4 [-19;12] | .65 | -3 [-13;7] | .54 | 3 [-9;15] | .60 |
| **Sports** | 6 [-1;6] | .001 | 6 [2;10] | .003 | 3 [-1;6] | .12 | 2 [-2;6] | .40 | 3 [0.2;6] | .04 | 4 [1;7] | .008 |

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Transportation** | -1 [-5;3] | .49 | 0.1 [-4;4] | .95 | 1 [-3;5] | .73 | 1 [-3;5] | .73 | -2 [-5;1] | .19 | -1 [-4;2] | .72 |
| **Inactivity** | -2 [-6;2] | .26 | -0.1 [-5;5] | .98 | -1 [-4;3] | .71 | 2 [-3;6] | .54 | -1 [-4;2] | .35 | -2 [-5;2] | .41 |

A positive mean value indicates that the last-mentioned group has the highest mean. Visit 2, the 29$^{th}$ gestational week; visit 3, the 29$^{th}$ gestational week. 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.

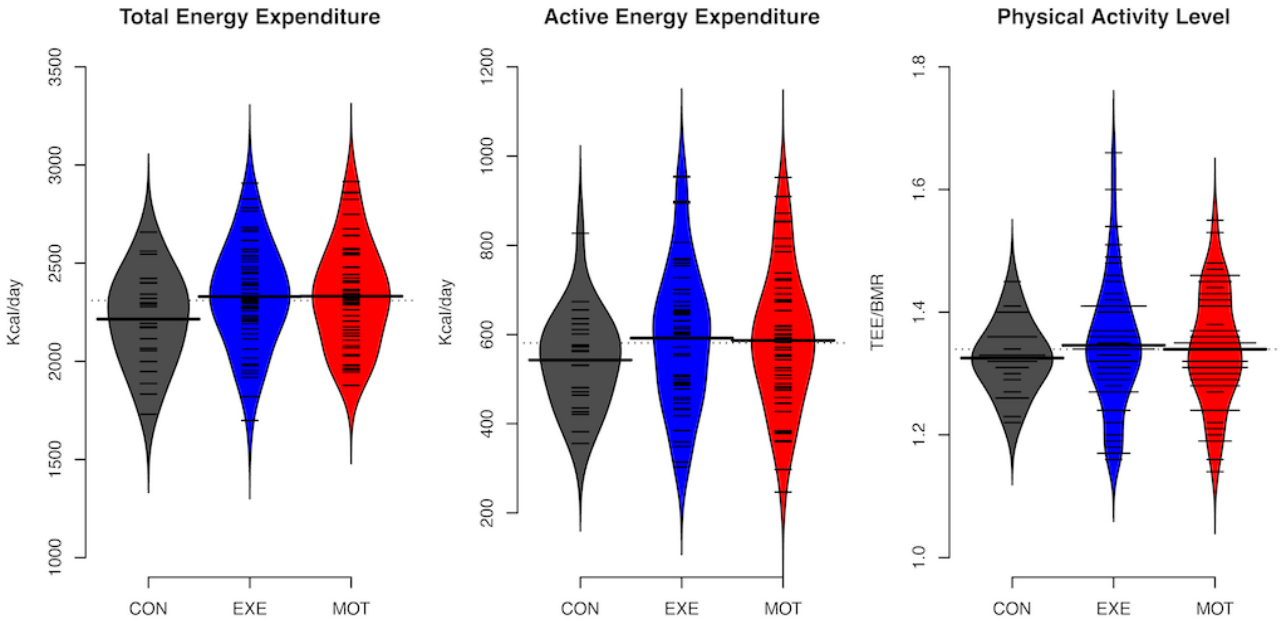
Multimedia Appendix 4. Pregnancy Physical Activity Questionnaire outcome descriptive statistics.

| | CON | | | | | EXE | | | | | MOT | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Visit 1 | Visit 2 | Visit 3 | Time effect visit 1 - visit 2 (*P*) | Time effect visit 1 - visit 3 (*P*) | Visit 1 | Visit 2 | Visit 3 | Time effect visit 1 - visit 2 (*P*) | Time effect visit 1 - visit 3 (*P*) | Visit 1 | Visit 2 | Visit 3 | Time effect visit 1 - visit 2 (*P*) | Time effect visit 1 - visit 3 (*P*) |
| | 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 (.34) | -29 (.001) | 150 (49) | 151 (50) | 136 (56) | 1 (.88) | -14 (.05) | 157 (52) | 155 (52) | 127 (45) | -2 (.83) | -30 (<.001) |
| **Activity of ≥ light intensity** | 147 (44) | 139 (44) | 117 (50) | -8 (.25) | -30 (<.001) | 135 (48) | 138 (49) | 121 (54) | 3 (.59) | -14 (.03) | 142 (50) | 140 (55) | 112 (47) | -2 (.85) | -30 (<.001) |
| **Intensity (MET-h/week)** | | | | | | | | | | | | | | | |
| **Sedentary** | 13 (10) | 15 (13) | 15 (12) | 2 (.32) | 2 (.25) | 15 (12) | 12 (8) | 15 (12) | 3 (.07) | 0 (.31) | 14 (14) | 14 (14) | 16 (14) | 0 (.92) | 2 (.036) |
| **Light** | 112 (35) | 106 (34) | 91 (45) | -6 (.16) | -21 (<.001) | 98 (34) | 96 (33) | 81 (34) | -2 (.35) | -17 (<.001) | 108 (37) | 104 (41) | 82 (34) | -4 (.38) | -26 (<.001) |
| **Moderate** | 33 (21) | 32 (21) | 26 (20) | -1 (.91) | -7 (.30) | 36 (30) | 40 (29) | 37 (36) | 4 (.17) | 1 (.63) | 35 (27) | 35 (25) | 29 (22) | 0 (.74) | -6 (.21) |
| **Vigorous** | 1 (3) | 1 (2) | 2 (5) | 0 (.97) | 1 (.56) | 1 (3) | 2 (4) | 2 (3) | 1 (.09) | 1 (.89) | 1 (2) | 3 (5) | 2 (5) | 2 (.002) | 1 (.03) |
| **Type (MET-h/week)** | | | | | | | | | | | | | | | |
| **Household** | 65 (36) | 63 (35) | 59 (31) | -2 (.84) | -6 (.42) | 54 (34) | 57 (39) | 56 (35) | 3 (.35) | 2 (.43) | 64 (44) | 60 (39) | 57 (36) | -4 (.36) | -7 (.18) |
| **Occupational** | 56 (29) | 49 (29) | 34 (32) | -7 (.13) | -22 (<.001) | 57 (37) | 47 (36) | 31 (42) | -10 (.02) | -26 (<.001) | 56 (32) | 50 (31) | 28 (30) | -6 (.14) | -28 (<.001) |

| | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Sports** | 7 (7) | 9 (7) | 9 (10) | 2 (.06) | 2 (.14) | 7 (7) | 15 (11) | 15 (10) | 8 (<.001) | 8 (<.001) | 5 (5) | 11 (9) | 10 (10) | 6 (<.001) | 5 (<.001) |
| **Transportation** | 14 (9) | 14 (8) | 12 (10) | 0 (.79) | -2 (.32) | 13 (8) | 13 (13) | 12 (11) | 0 (.56) | -1 (.27) | 14 (9) | 15 (11) | 13 (9) | 1 (.37) | -1 (.34) |
| **Inactivity** | 15 (11) | 17 (13) | 18 (11) | 2 (.49) | 3 (.19) | 16 (13) | 15 (9) | 18 (12) | -1 (.27) | -2 (.10) | 16 (16) | 17 (14) | 19 (16) | 1 (.90) | 3 (.007) |

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 29$^{th}$ gestational week; visit 3, the 35$^{th}$ gestational week. 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.

Multimedia Appendix 5



Multimedia Appendix 6

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

Multimedia Appendix 7

| Adverse events | ALL n=220 | CON n=45 | EXE n=87 | MOT n=87 |
|---|---|---|---|---|
| **All** | | | | |
| ≥ 1 adverse event, n (%) | 141 (64) | 28 (62) | 58 (67) | 55 (63) |
| **Pregnancy, puerperium and perinatal conditions, n (%)** | 118 (54) | 22 (49) | 49 (56) | 47 (54) |
| Foetal hypokinesia, n (%) | 47 (21) | 7 (16) | 23 (26) | 17 (20) |
| Low back and pelvic girdle pain, n (%) | 41 (19) | 4 (9) | 19 (22) | 18 (21) |
| Uterine contractions during pregnancy, n (%) | 20 (9) | 1 (2) | 10 (12) | 9 (10) |
| GDM, n (%) | 13 (6) | 2 (4) | 5 (6) | 6 (7) |
| Small for dates baby (<-1.28 SD), n (%) | 11 (5) | 3 (7) | 1 (1) | 7 (8) |
| Large for dates baby (>1.28 SD), n (%) | 13 (6) | 1 (2) | 7 (8) | 5 (6) |
| Preeclampsia/gestational hypertension/HELLP/eclampsia (GA≥34 weeks), n (%) | 11 (5) | 2 (4) | 5 (6) | 4 (5) |

| | | | | |
|---|---|---|---|---|
| Premature delivery (GA 34+0 - 36+6 weeks), n (%) | 3 (1) | 2 (4) | 1 (1) | 0 (0) |
| Cholestasis of pregnancy, n (%) | 3 (1) | 0 (0) | 0 (0) | 3 (3) |
| Foetal malformation, n (%) | 3 (1) | 2 (4) | 1 (1) | 0 (0) |
| Hyperemesis gravidarum, n (%) | 2 (0.9) | 1 (2) | 0 (0) | 1 (1) |
| Threathened preterm labor, n (%) | 1 (0.5) | 0 (0) | 0 (0) | 1 (1) |
| Gestational oedema, n (%) | 1 (0.5) | 0 (0) | 0 (0) | 1 (1) |
| **Reproductive system and breast disorders, n (%)** | 17 (8) | 4 (9) | 6 (7) | 7 (8) |
| Vaginal haemorrhage, n (%) | 17 (8) | 4 (9) | 6 (7) | 7 (8) |
| Ovarian rupture, n (%) | 1 (0.5) | 0 (0) | 1 (1) | 0 (0) |
| **Infections and infestations, n (%)** | 21 (10) | 7 (16) | 6 (7) | 8 (9) |
| Urinary tract infection, n (%) | 10 (5) | 3 (7) | 3 (3) | 4 (5) |
| Beta haemolytic streptococcal infection, n (%) | 6 (3) | 3 (7) | 2 (2) | 1 (1) |
| Other, n (%) | 6 (3) | 1 (2) | 2 (2) | 3 (3) |
| **Accidents and Injuries, n (%)** | 7 (3) | 2 (4) | 3 (3) | 2 (2) |
| Unrelated to intervention, n (%) | 6 (3) | 2 (4) | 2 (2) | 2 (2) |
| Related to intervention*, n (%) | 1 (0.5) | 0 (0) | 1 (1) | 0 (0) |
| **Skin and subcutaneous tissue disorders, n (%)** | 12 (6) | 2 (4) | 3 (3) | 7 (8) |
| Rash, n (%) | 9 (4) | 2 (4) | 3 (3) | 4 (5) |
| Prurigo, n (%) | 3 (1) | 0 (0) | 0 (0) | 3 (3) |
| **Nervous system disorders, n (%)** | 10 (5) | 1 (2) | 5 (6) | 4 (5) |
| Migraine, n (%) | 5 (2) | 0 (0) | 1 (1) | 4 (5) |
| Headache, n (%) | 2 (0.9) | 1 (2) | 1 (1) | 0 (0) |
| Dizziness, n (%) | 2 (0.9) | 0 (0) | 1 (1) | 1 (1) |
| Carpal tunnel syndrome, n (%) | 2 (0.9) | 0 (0) | 2 (2) | 0 (0) |
| **Psychiatric disorders, n (%)** | 4 (2) | 1 (2) | 0 (0) | 3 (3) |
| **Gastrointestinal disorders, n (%)** | 3 (1) | 0 (0) | 2 (2) | 1 (1) |
| Constipation, n (%) | 2 (0.9) | 0 (0) | 2 (2) | 0 (0) |
| Abdominal pain upper, n (%) | 1 (0.5) | 0 (0) | 0 (0) | 1 (1) |
| **Other, n (%)** | 9 (4) | 3 (7) | 3 (3) | 3 (3) |

Multimedia Appendix 8

| Serious adverse events | ALL n=220 | CON n=45 | EXE n=87 | MOT n=87 |
|---|---|---|---|---|
| **All** | | | | |
| ≥ 1 serious adverse event, n (%) | 17 (8) | 3 (7) | 6 (7) | 8 (9) |
| Serious adverse events, n (%) | 20 (9) | 3 (7) | 6 (7) | 11 (13) |
| **Pregnancy, puerperium and perinatal conditions, n (%)** | 16 (7) | 3 (7) | 6 (7) | 7 (8) |
| Large for gestational age (>2 SD), n (%) | 5 (2) | 1 (2) | 0 (0) | 4 (5) |
| Small for gestational age (<-2 SD), n (%) | 4 (2) | 1 (2) | 2 (2) | 1 (1) |
| Missed abortion, n (%) | 3 (1) | 0 (0) | 2 (2) | 1 (1) |
| Premature delivery (GA<34 weeks), n (%) | 3 (1) | 1 (2) | 0 (0) | 2 (2) |
| Shoulder dystocia, n (%) | 2 (0.9) | 0 (0) | 1 (1) | 1 (1) |
| Pelvic haematoma obstetric, n (%) | 1 (0.5) | 0 (0) | 1 (1) | 0 (0) |
| Preeclampsia/gestational hypertension/HELLP/eclampsia (GA<34 weeks), n (%) | 1 (0.5) | 0 (0) | 0 (0) | 1 (1) |
| **Accidents and injuries** | | | | |
| Car accident, n (%) | 1 (0.5) | 0 (0) | 0 (0) | 1 (1) |

# Paper 4

**Effects of two physical activity interventions on sleep and sedentary time in pregnant women**

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**Abstract**

Pregnancy is often associated with poor sleep and high sedentary time (SED). We investigated the effect of physical activity (PA) interventions on sleep and SED in pregnant women. A secondary analysis of a randomised controlled trial (n=219) explored the effect of structured supervised exercise training (EXE) or motivational counselling on PA (MOT) compared to standard prenatal care (CON) on sleep and SED during pregnancy. Three times during pregnancy, sleep was determined by the Pittsburgh Sleep Quality Index (PSQI) and SED by the Pregnancy Physical Activity Questionnaire (PPAQ). Also, a wrist-worn consumer activity tracker measured sleep and SED continuously. Data from the activity tracker confirmed that sleep time decreases, and SED increases by approx. 30 and 24 min/day, respectively, from baseline (maximum gestational age (GA) week 15) to delivery. Compared to CON, the global PSQI score was better for EXE in GA week 28 (-0.8 [-1.5; -0.1], *P*=.031) and for both EXE and MOT in GA week 34 (-1 [-2; -0.5], *P*=.002; -1 [-2; -0.1], *P*=.026). In GA week 28, SED (hr/day) from PPAQ was lower in EXE compared to both CON and MOT (-0.69 [-1; -0.0], *P*=.049; -0.6 [-1.0; -0.02], *P*=.042). In conclusion, PA interventions during pregnancy improved sleep quality and reduced SED.

***Trial registration***

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

***Keywords***

Consumer activity tracker, FitMum, Maternal health, Pittsburgh Sleep Quality Index, Pregnancy Physical Activity Questionnaire, Randomised control trial.

## Introduction

Pregnant women benefit from physical activity (PA) during pregnancy, including a decreased risk of excessive gestational weight gain, preterm birth, gestational diabetes mellitus, preeclampsia, delivery complications, and postpartum depression [1,2]. However, poor sleep quality during pregnancy might contradict the benefits [3,4]. Pregnancy-induced physiological and psychological changes include increased body weight, urination, anxiety, and stress [5]. Likewise, sleep is negatively affected, and sleep disturbances during pregnancy are more prevalent than in the general population [6]. One of the non-pharmaceutical ways to improve healthy sleep patterns in the general population is to engage in PA [7], and this is also true during pregnancy [8,9]. PA level is positively associated with sleep quality during pregnancy, and PA at both low and moderate intensity one to three days per week has been shown to improve sleep outcomes [8]. Yet, the evidence of which strategies of PA improve sleep during pregnancy is limited, and more robust randomised controlled trials (RCTs) that cover all trimesters are therefore needed [8,10].

Sedentary behaviour is considered any physical behaviour that does not significantly raise energy expenditure above that of resting (less than 1.5 metabolic equivalence of task), such as sleeping, sitting, lying down, watching television, and other screen-based activities [11]. The World Health Organization's recommendations for pregnant women in 2020 replaced those issued in 2010 regarding PA and, for the first time, advised reducing the sedentary time (SED) [12]. A rising body of evidence suggests that SED may adversely affect adults' health and be a risk factor for diabetes, cardiovascular disease, and death [13,14]. In addition, the prevalence of SED among pregnant women is higher than in the general population; pregnant women tend to spend more than 50% of their day as SED [15]. Thus, studies are needed to generate knowledge about the effect of PA interventions on SED during pregnancy.

Several PA interventions during pregnancy have focused on increasing moderate-to-vigorous-intensity PA (MVPA) and PA in general and evaluating the health effects of these interventions. However, few have focused on exploring the effect of PA interventions on sleep quantity and quality and SED during pregnancy [16]. We conducted a single-site three-armed RCT, the FitMum study, to evaluate the effects of offering structured supervised exercise training (EXE) or motivational counselling on PA (MOT) compared to standard prenatal care (CON) for inactive pregnant women [17]. Overall, we found that offering EXE was more effective than CON in increasing MVPA among pregnant women, whereas offering MOT was not [18]. The aim of the present secondary analysis was to assess the effect of the FitMum PA interventions on sleep quantity and quality and SED.

## Methods

### *Ethics and public involvement*

The FitMum 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 and is registered at ClinicalTrials.gov (NCT03679130). While designing the study, 27 semi-structured interviews with Danish pregnant women, midwives, and obstetricians were conducted. Before participants were included in the study, written informed consent was obtained.

### *Setting*

This study was conducted at the Department of Gynaecology and Obstetrics at the public hospital Copenhagen University Hospital – North Zealand, Hilleroed. Participation in the FitMum RCT was free of charge. The first participant was included in October 2018, and the last participant gave birth in May 2021.

### *Participants and study design*

Two hundred twenty healthy pregnant women were included. Inclusion criteria were obtaining written informed consent, being 18 years or older, having a maximum gestational age (GA) of 15 weeks, having an ultrasonic-confirmed viable intrauterine pregnancy, having a body mass index of 18.5–45 kg/m$^2$, and weighing <150 kg (pre-pregnancy weight or first measured weight in pregnancy), being able to wear a wrist-worn activity tracker 24/7 until delivery, and having a smartphone. Exclusion criteria were structured exercise at moderate-to-vigorous intensity for more than one hour per week during early pregnancy, previous preterm delivery, obstetric or medical complications, multiple pregnancies, non-Danish speaking, or alcohol or drug abuse.

### *Interventions*

The aims and primary results of the FitMum study have been published elsewhere [17,18]. Briefly, we investigated two different strategies to increase PA in pregnant women with low PA levels and assessed the health effects of PA. The primary outcome was MVPA, measured by a Garmin Vivosport activity tracker. The FitMum RCT study had three study arms: 1) supervised structured exercise training (EXE), 2) motivational counselling on PA (MOT), and 3) standard prenatal care (CON). Participants in EXE and MOT were encouraged to be physically active at moderate intensity for at least 30 minutes daily. The EXE participants were offered 1-hour supervised group sessions three times a week, two at the gym and one in the swimming pool. The MOT intervention consisted of weekly SMS reminders, four individual counselling sessions, and three group counselling sessions during pregnancy.

Participants in all three study groups had three visits where sleep and SED were investigated: at baseline before GA week 15, at GA week 28, and at GA week 34. During the COVID-19 pandemic, restrictions in Denmark started on March 11, 2020, and the interventions shifted to online sessions. The FitMum study had no intervention component regarding sleep or SED.

### *Outcomes*

#### Sleep quantity and quality by Pittsburgh Sleep Quality Index

The Danish version of the self-administered Pittsburgh Sleep Quality Index (PSQI) questionnaire [19,20] was digitally sent to the participants at baseline, GA week 28, and GA week 34. PSQI has been validated among pregnant women [21]. The PSQI has 19 questions that measure seven components: 1) sleep quality, 2) sleep latency, 3) sleep duration, 4) sleep efficiency, 5) sleep disturbance, 6) use of sleep medication, and 7) daytime dysfunction. The sum of the seven components forms the global PSQI score, ranging from 0 to 21, where a higher score indicates less sleep quality. A global PSQI score below 5 denotes a "good sleeper", and a score above 5 indicates a “poor sleeper” [22].

#### Sedentary time by the Pregnancy Physical Activity Questionnaire

The Pregnancy Physical Activity Questionnaire (PPAQ) was designed and developed to determine PA intensity and duration during pregnancy [23]. We translated PPAQ to Danish and validated it in a Danish pregnant population [24]. For SED, we calculated time spent on sedentary activities from five questions as recommended [25,26] instead of two as done originally. PA duration and metabolic equivalence of task values were calculated according to the PPAQ developers’ guidelines; each answer in PPAQ corresponds to time spent in an activity multiplied by the intensity of the activity [27]. PPAQ was digitally sent to the participants at baseline, GA week 28, and GA week 34.

#### Sleep and sedentary time by the activity tracker

The activity tracker data management and measurement details are published elsewhere [17,28]. In brief, all participants were given a consumer activity tracker with a built-in heart rate monitor and an accelerometer (Garmin Vivosport, Garmin International) [29], which had to be worn on the non-dominant wrist 24/7 from the inclusion until giving birth. Participants were instructed to sync the activity tracker data every day, and if a participant was not syncing for more than seven days, an e-mail reminder would be sent. We monitored data flow and synchronisation from the activity tracker through a research platform (Fitabase, San Diego, US). In contrast to the PSQI and PPAQ, the activity tracker determined sleep and SED continuously. The activity tracker combines heart rate and body movement data to determine

when participants fall asleep, awake time and sleep stage during typical sleeping hours set by the user (not including nap time) [30]. We calculated sleep time as the sum of all sleep stages.

Moreover, the activity tracker shows PA daily values in a detailed log (Epoch log). From the Epoch log, a categorisation of time is sorted into sedentary, active, or highly active by algorithms in the activity tracker. Sedentary is defined as little to no activity monitored; accordingly, minimal movement, sitting, resting, and sleeping are considered sedentary behaviour [29]. We calculated awake SED by subtracting sleep time from total SED. Data from the activity tracker was handled and included in the analysis according to predefined wear time criteria [28].

***Statistical Analysis***

For the PSQI and PPAQ outcomes, a constrained linear mixed model was fitted with the observation times as a factor [31], and the inference was performed based on a cluster bootstrap procedure. The between-group effects were reported as estimated differences in means. Intention-to-treat analyses using all randomised participants were performed for the outcomes from the activity tracker [28]. Missing observations in activity 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, sleep, SED, and parity), and the random forest imputation model from the mice R package [32]. For the activity tracker analysis, a constrained linear mixed model has been used of the mean values for baseline (6 days), randomisation to GA week 28 (approx. 110 days), GA week 28 to GA week 34 (approx. 42 days), and GA week 34 to delivery (approx. 40 days), respectively. Sleep and SED before and during the COVID-19 pandemic were compared within groups with a linear regression model. All statistical analyses were performed using R version 4.2.2 [33]. Data are presented as means ± standard deviation for symmetric distributions and medians (interquartile ranges) for skewed data. The level of statistical significance was 5%, with 95% confidence intervals (CI) given for all reported estimates.

## Results

***Participant characteristics***

219 women were randomised to CON (n=45), EXE (n=87), or MOT (n=87). At baseline, participants had a median GA of 12.9 weeks (9.4 - 13.9), age was 31.5 ± 4.3 years, and body weight was 75.4 ± 15.3 kg. The median pre-pregnancy body mass index was 24.1 (21.8 - 28.7) kg/m$^2$. Participants wore the activity tracker for a total of 24,519 days out of 31,646 potential days (77%). The median activity tracker wear time was 183 (4 - 232) days.

Lost to follow-up were 24% for CON, 15% for EXE and 20% for MOT from randomisation to delivery. The adherence to intervention participation was 1.3 [95% CI 1.1; 1.5] exercise sessions per week from randomisation to delivery for EXE, whereas MOT attended 5.2 [4.7; 5.7] counselling sessions from randomisation to delivery.

***Sleep quantity and quality by the Pittsburgh Sleep Quality Index***

PSQI was completed by 219 (100%), 180 (82%), and 165 (75%) participants at baseline, GA week 28, and GA week 34, respectively. The mean global PSQI score (6.4 ± 1.9) was above 5 for all three groups at baseline. When comparing the two intervention groups with CON, EXE scored lower (i.e., lower means better) in the global PSQI score at GA week 28 (-0.8 [-2; -0.1], *P*=.031) and GA week 34 (-1 [-2; -0.5], *P*=.002) (**Figure 1, Table 1**).

**Table 1:** Outcomes from the Pittsburgh Sleep Quality Index and sedentary time from the Pregnancy Physical Activity Questionnaire

| | **CON vs EXE** | | | | **CON vs MOT** | | | | **MOT vs EXE** | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | GA week 28 | | GA week 34 | | GA week 28 | | GA week 34 | | GA week 28 | | GA week 34 | |
| | 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 |
| **PSQI** | | | | | | | | | | | | |
| **Global PSQI score** | -0.8 [-2; -0.1] | **0.031** | -1 [-2; -0.5] | **0.002** | -0.3 [-1.0; 0.5] | 0.451 | -1.0 [-2; -0.1] | **0.026** | -0.5 [-0.1.1; 0.1] | 0.848 | -0.4 [-1.1; 0.3] | 0.309 |
| **Total sleep time (hr/day)** | 0.06 [-0.3; 0.41] | 0.727 | 0.1 [-0.3;0.5] | 0.702 | 0.11 [-0.24; 0.5] | 0.554 | 0.27 [-0.14; 0.7] | 0.191 | -0.04 [-0.3; 0.2] | 0.757 | -0.2 [-0.5; 0.1] | 0.234 |
| **Total time in bed (hr/day)** | -0.20 [-0.6;0.17] | 0.282 | -0.1 [-0.5;0.3] | 0.637 | -0.14 [-0.5; 0.2] | 0.474 | 0.02 [-0.4; 0.4] | 0.921 | -0.1 [-0.4; 0.2] | 0.686 | -0.1 [-0.4; 0.2] | 0.469 |
| **Subjective sleep quality** | 0.11 [ 0.1; 0.3] | 0.340 | 0.03 [-0.24;0.32] | 0.795 | 0.11 [-0.12; 0.35] | 0.341 | 0.1 [-0.2; 0.4] | 0.494 | -0.005 [-0.2; 0.2] | 0.961 | -0.05 [-0.30; 0.2] | 0.661 |
| **Sleep efficiency (%)** | 3 [-0.9; 7] | 0.133 | 3 [-2; 8] | 0.240 | 2.7 [-1.4; 6.9] | 0.199 | 3.7 [-1.3; 8.86] | 0.146 | 0.4 [-2.9; 3.8] | 0.804 | -0.8 [-4.7; 3.1] | 0.696 |
| **Sleep Disturbance** | -0.14 [-0.3;0.1] | 0.164 | -0.3 [-0.5;-0.05] | **0.019** | -0.07 [-0.3; 0.1] | 0.485 | -0.14 [-0.4; 0.11] | 0.279 | -0.1[-0.24; 0.1] | 0.388 | -0.2 [-0.3; 0.03] | 0.098 |
| **Sleep Medications** | -0.1 [-0.3; 0.07] | 0.246 | -0.1 [-0.3;0.1] | 0.324 | 0.0003 [-0.2; 0.2] | 0.997 | -0.02 [-0.2; 0.15] | 0.801 | -0.1 [-0.2; 0.04] | 0.153 | -0.1 [-0.2; 0.1] | 0.344 |
| **Sleep latency** | -0.33 [-0.7; 0.04] | 0.077 | -0.5 [-0.8; 0.05] | **0.027** | -0.2 [-0.6; 0.1] | 0.221 | -0.21 [-0.6; 0.2] | 0.325 | -0.09[0.4; -0.2] | 0.541 | - 0.25 [-0.5; 0.04] | 0.098 |
| **Daytime Dysfunction** | -0.03 [-0.3; 0.2] | 0.758 | -0.3 [-0.5; 0.00] | 0.052 | 0.20 [-0.03; 0.4] | 0.095 | -0.146 [-0.43; 0.14] | 0.313 | -0.2 [-0.4; -0.04] | **0.017** | -0.13 [-0.32; 0.1] | 0.186 |
| **PPAQ** | | | | | | | | | | | | |

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Sedentary time hr/day** | - 0.69 [-1; -0.0] | **0.049 8** | - 0.05 [-1 - 0.9] | 0.9 16 | -0.11 [- 0.8 - 0.6] | 0.7 54 | 0.1 [-0.8 - 1.2] | 0.7 76 | -0.6 [- 1.0; - 0.02] | **0.0 42** | -0.1 [- 1.0; 0.6] | 0.7 76 |

Comparison between groups on sleep outcomes from Pittsburgh Sleep Quality Index (PSQI) and sedentary time from the Pregnancy Physical Activity Questionnaire (PPAQ). A positive mean value indicates that the last-mentioned group has the highest mean. CI, confidence interval; CON, standard care; EXE, structured supervised exercise training; GA, gestational age; hr, hour; MOT, motivational counselling on physical activity.

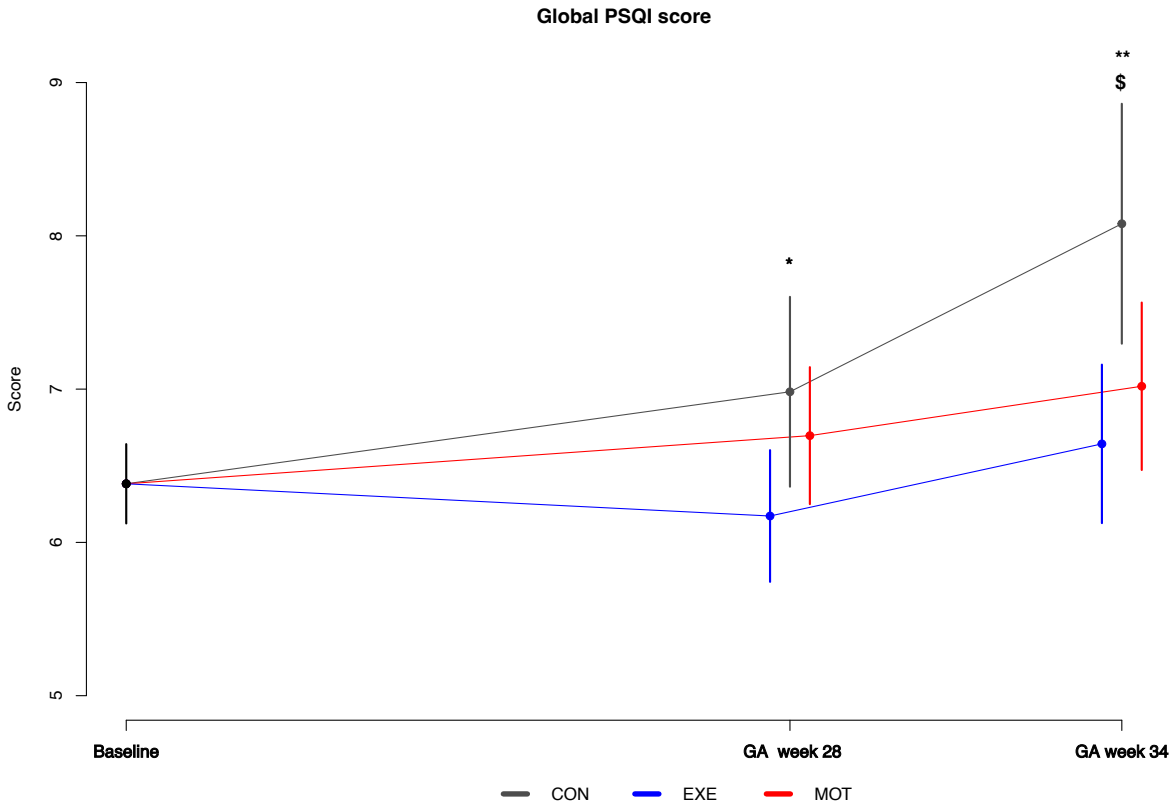


**Figure 1**: Baseline-constrained comparison between groups based on the means of the Pittsburgh Sleep Quality Index global score. Baseline, gestational age of maximum 15 weeks; CON, standard care; EXE, structured supervised exercise training; GA, gestational age; MOT, motivational counselling on physical activity. *EXE compared to CON at GA week 28 (P=.031), **EXE compared to CON at GA week 34 (P=.002), $ MOT compared to CON at GA week 34 (P=.026).

Also, MOT scored lower than CON at GA week 34 (-1 [-2; -0.1], *P*=.026) (**Figure 1, Table 1**). There were no significant differences, except for sleep latency and sleep disturbance, when comparing EXE and MOT to CON for the individual PSQI outcomes **(Table 1)**. At GA week 34, EXE had lower sleep latency (-0.5 [-0.8; 0.05], *P*=.027) and less sleep disturbance (-0.3 [-0.5; -0.05], *P*=.019) compared to CON. When comparing EXE to MOT, there were no significant differences for the individual PSQI outcomes, except that EXE scored lower than MOT for daytime dysfunction at GA week 28 (-0.2 [-0.4; -0.04], *P*=.017). A full comparison between the three groups is shown in **Table 1**. The average sleep time (hr/day) decreased for

all participants (time effect) from baseline to GA week 34 (-0.24 [-0.4; -0.1], *P*=.001) (approx. 14 min/day).

***Sedentary time by the Pregnancy Physical Activity Questionnaire***

At GA week 28, SED (hr/day) from PPAQ was lower for EXE compared to both CON (-0.69 [-1; -0.0], *P*=.0498) and MOT (-0.6 [-1.0; -0.02], *P*=.042) **(Figure 2, Table 1**).

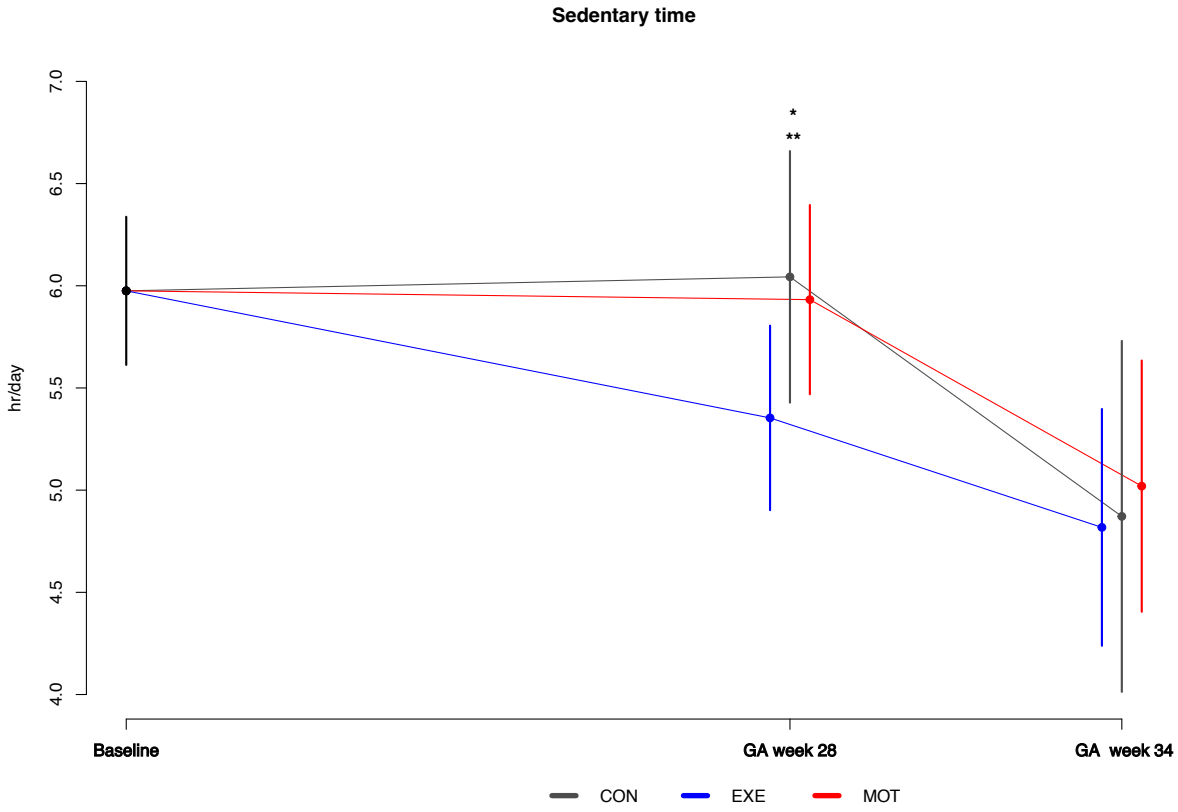


**Figure 2**: Baseline-constrained comparison between groups based on the means of sedentary time from the Pregnancy Physical Activity Questionnaire. Baseline, gestational age of maximum 15 week; CON, standard care; EXE, structured supervised exercise training; GA, gestational age; hr, hour; MOT, motivational counselling on physical activity. *EXE compared to CON at GA week 28 (P=.0498), **EXE compared to MOT at GA week 28 (P=.042).

Additionally, average SED (hr/day) decreased among all participants (time effect) from baseline to GA week 34 (-1.1 [-1.5; -0.67], *P* < .001) **(Figure 2)**.

***Sleep and sedentary time by the activity tracker***

The unadjusted average of sleep time (hr/day) for all participants was (8.2 [8.1; 8.3]), (8.0 [7.9; 8.1]) and (7.8 [7.8; 7.9]), respectively, at GA week 28, GA week 34 and delivery. Moreover, the unadjusted average SED (hr/day) for all participants was (13.1 [12.9; 13.2]), (13.2 [13.0; 13.3]) and (13.5 [13.2; 13.6]), respectively, at GA week 28, GA week 34 and delivery. However, sleep time and SED did not differ significantly between groups (**Table 2 and Figure 3).**

**Table 2**: Sleep and sedentary time from activity tracker

| | CON vs EXE | | | | | | CON vs MOT | | | | | | MOT vs EXE | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | GA week 28 | | GA week 34 | | Delivery | | GA week 28 | | GA week 34 | | Delivery | | GA week 28 | | GA week 34 | | 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 | Differences [95% CI] | p-value | Differences [95% CI] | p-value | Differences [95% CI] | p-value |
| **Tracker outcomes** | | | | | | | | | | | | | | | | | | |
| **Total sleep time (hr/day)** | -0.01 [-0.2; 0.2] | 0.890 | 0.05 [-0.1; 0.3] | 0.603 | -0.07[-0.3; 0.2] | 0.573 | 0.02 [-0.2; 0.2] | 0.833 | 0.15 [-0.1; 0.4] | 0.151 | 0.1 [-0.1to 0.4] | 0.366 | -0.03 [-0.2; 0.1] | 0.669 | -0.1[-0.3; 0.1] | 0.247 | -0.08 [-0.4; 0.02 | 0.072 |
| **Sedentary time (hr/day)** | 0.001 [-0.2; 0.2] | 0.993 | 0.03 [-0.3; 0.4] | 0.845 | 0.1 [-0.3; 0.4] | 0.609 | -0.1 [-0.3; 0.1] | 0.534 | -0.2[-0.5; 0.1] | 0.234 | -0.1 [-0.5; 0.2] | 0.285 | 0.1 [-0.1; 0.2] | 0.437 | 0.2[-0.04; 0.5] | 0.095 | 0.3 [-0.03; 0.5] | 0.053 |

Comparison between groups based on imputed activity tracker datasets (intention to treat analysis) from randomisation (gestational age of maximum 15 week), GA week 28, GA week 34 and delivery, respectively. A positive mean value indicates that the last-mentioned group has the highest mean. CI, confidence interval; CON, standard care; EXE, structured supervised exercise training; GA, gestational age; hr, hour; MOT, motivational counselling on physical activity.

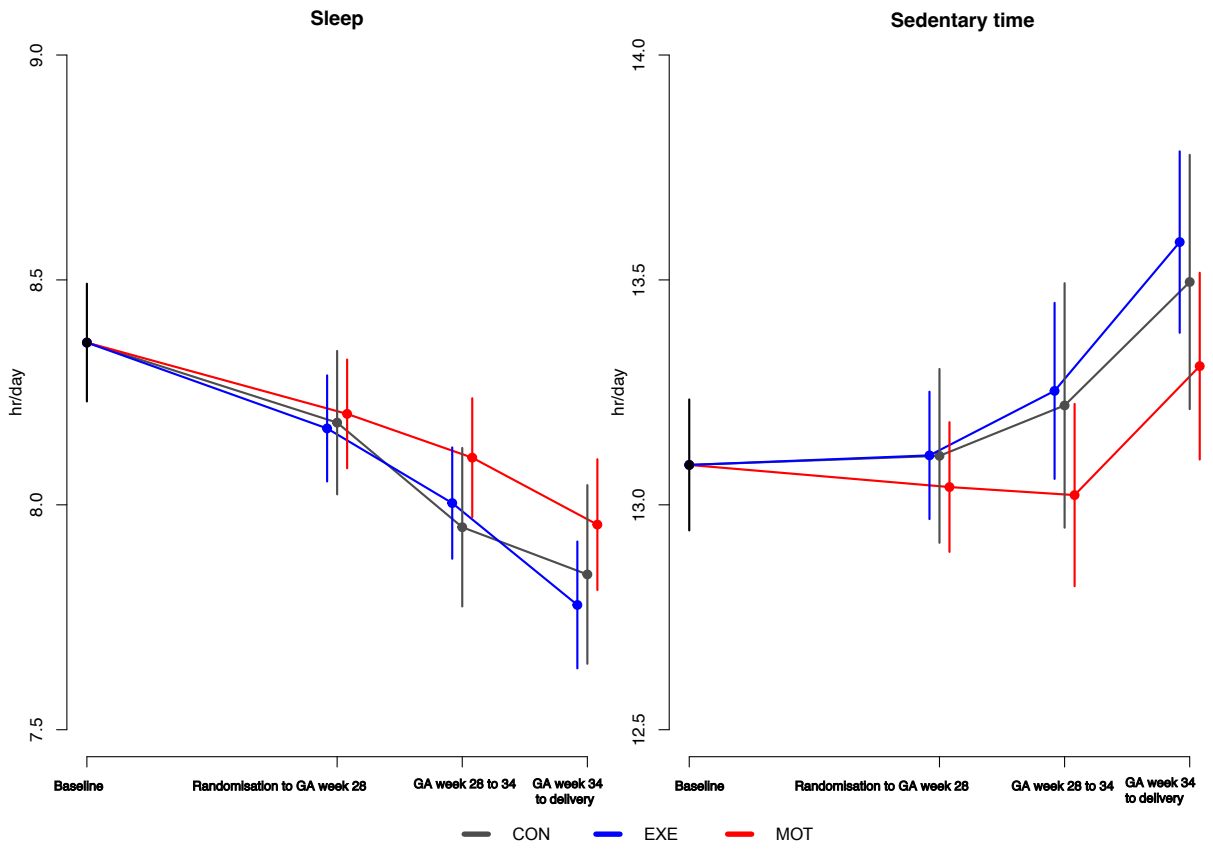


**Figure 3**: Baseline-constrained comparison between groups based on the activity tracker's mean of total sleep and sedentary time. Baseline, gestational age of maximum 15 week; CON, standard care; EXE, structured supervised exercise training; GA, gestational age. hr, hour; MOT, motivational counselling on physical activity.

Compared to the baseline, the average sleep time (hr/day) decreased for all participants at GA week 28 (-0.2 [-0.3; -0.1], *P* <.001), GA week 34 (-0.4 [-0.4; -0.2], *P* < .001), and delivery (-0.5 [-0.6; -0.4], *P* < .001) (approx. 12, 18 and 30 min/day, respectively). On the other hand, the average SED (hr/day) increased among the participants as the pregnancy progressed and was significantly higher at delivery compared with baseline (0.4 [0.2; 0.5], *P*< .001) (approx. 24 min/day).

***COVID-19 impact on sleep and sedentary time as measured by the activity tracker***

No overall differences in sleep time and SED from randomisation to delivery were found between participants ending the intervention before the COVID-19 pandemic (physical intervention only, n=120) and those included and ending the intervention during the COVID-19 pandemic (online intervention only, n=63). However, EXE participants who were offered the online intervention during the COVID-19 pandemic had more SED (hr/day) than those offered the physical intervention (0.4 [-0.1; 0.8], *P*=.032) (approx. 25 min/day) (**Figure 4**).

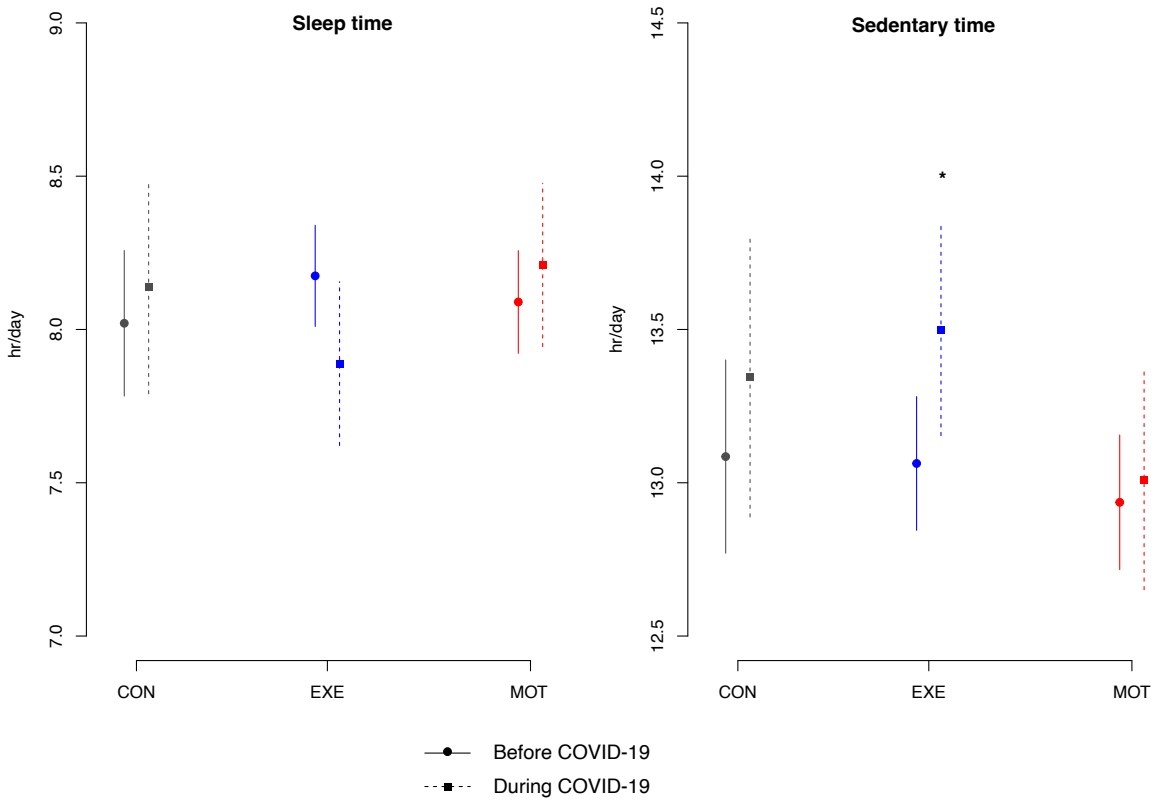


**Figure 4**: Average and 95% confidence interval of total sleep time and sedentary time before COVID-19 [physical intervention only, participants (n=120) started and finished the intervention before COVID-19] (full line) and during COVID-19 [online intervention only, participants (n=63)] (dotted line)], respectively. CON, standard care; EXE, structured supervised exercise training; hr, hour; MOT, motivational counselling on physical activity. *EXE who received the physical intervention compared to EXE who received online intervention from randomisation (gestational age of maximum 15 week) to delivery (P=.032).

### *Comparison of sleep time from the activity tracker and the Pittsburgh Sleep Quality Index*

We compared sleep time from the activity tracker and PSQI. At baseline, GA week 28, and GA week 34, the correlations were weak (r = 0.17, 0.27, and 0.31 (*P*= .01, .001 and .001), respectively). The mean biases for sleep time between the activity tracker and PSQI were 1.2, 1.0, and 1.0 hr/day, respectively, with higher values reported by the activity tracker than by the PSQI (**Figure 5**).

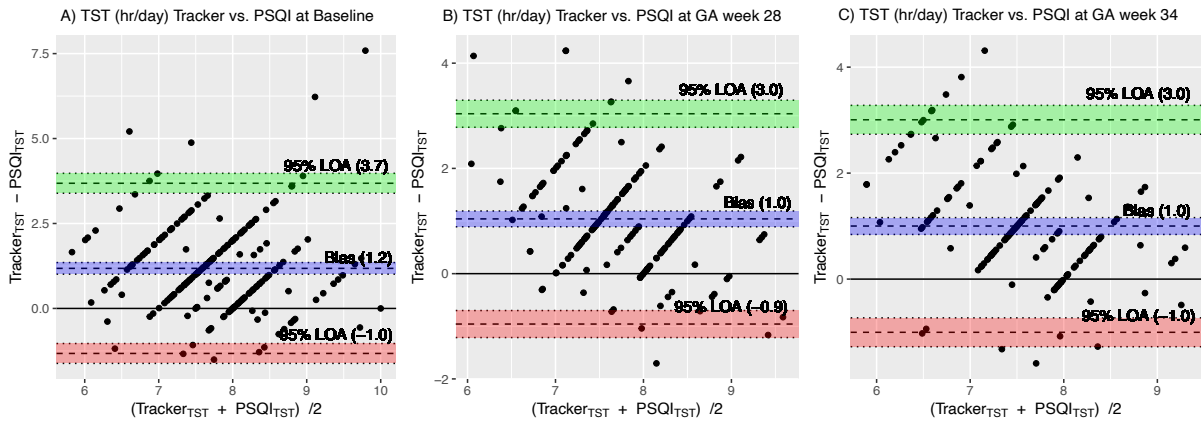

**Figure 5**: Differences of the total sleep time between the Pittsburgh Sleep Quality Index (PSQI) and the activity tracker vs. the average of sums at the gestational age of maximum 15 week (A), GA week 28 (B), GA week 34s (C). hr, hour; GA, gestational age; TST, total sleep time; LOA, the limit of agreements.

## Discussion

In this secondary analysis of the FitMum RCT, we found that the overall sleep quality as determined by PSQI was better in EXE than CON at GA week 28 and better in both EXE and MOT than CON at GA week 34. Moreover, EXE had less SED than MOT and CON at GA week 28, according to PPAQ. The activity tracker showed no significant differences between groups in sleep time and SED. However, sleep time decreased as the pregnancy progressed. SED constituted more than half of the day and increased toward the end of the pregnancy. Moreover, participants in EXE who received the intervention online due to COVID-19 restrictions had more SED than those who received the physical EXE intervention before COVID-19.

### *Effectiveness of physical activity interventions on sleep quality as determined by the Pittsburgh Sleep Quality Index*

We observed a relatively high mean global PSQI score at baseline, which is similar to other findings among pregnant women [34–36]. In alignment with our results, a recent systematic review showed that PA level was positively associated with sleep quality as determined by the PSQI during pregnancy [8]. In addition, a systematic review and meta-analysis of RCTs conducted among pregnant women revealed that sleep quality was improved among exercise group participants when determined by the PSQI [37]. Like our findings, an RCT of an 8-week supervised home tele-based Pilates program 50 min twice a week (n=7) and control (n=7) during pregnancy showed that PSQI global scores were significantly lower in the intervention compared to the control group [38]. In contrast to our findings, an RCT among Danish pregnant women with or at high risk of depression found no difference in the global PSQI score after 12 weeks of supervised group exercise (70 min twice a week) starting from GA 17–22 weeks [36]. However, women participating in >74% of the exercise sessions (per protocol analysis) had significantly lower mean global PSQI scores than women in the control group.

### *Effectiveness of physical activity interventions on sedentary time as determined by the Pregnancy Physical Activity Questionnaire*

The PPAQ showed lower SED measured in EXE compared to MOT and CON, which contradicts other findings. A 12-week unsupervised exercise intervention in early pregnancy did not affect SED [39]. Moreover, pregnant women randomised to 12 weeks of supervised exercise three times a week spent more time performing MVPA than the control group, but SED reported by PPAQ did not differ between groups [40]. Also, 90 pregnant women were

randomised to an eight-week educational intervention on WhatsApp to improve PA or to a control group. PA level was increased in the intervention group, but SED measured by PPAQ did not differ between groups [41]. These contradictory results might be because we used five instead of two items from PPAQ to compute SED as recently recommended [25,26]. In this way, we increased the sensitivity of the questionnaire.

***Sleep and sedentary time as determined by the activity tracker***

Like others, we found that sleep decreases [3–5] and SED may increase as pregnancy progresses [16,42]. Notably, objective methods have not been used in previous RCT studies investigating the effects of PA on sleep among pregnant women [8,37]. A systematic review investigating sedentary behaviours during pregnancy found that despite the wide disparity between sedentary behaviour definitions and measurement techniques, pregnant women spent more than half of their day in SED [15], which aligns with our findings. In addition, few studies examined sleep using a consumer activity tracker during most of the pregnancy period. An observational study that used Fitbit Flex to examine pregnant women's sleep duration discovered a strong inverse correlation between sleep and GA [43].

***Sedentary time measured by the Pregnancy Physical Activity Questionnaire and the activity tracker***

We observed that SED increased during pregnancy when measured by the activity tracker (approx. 24 minutes/day) and decreased when measured by PPAQ (approx. 1 hr/day). This might be explained by two previous findings from the FitMum study. First, in a validation study, we found a significant underestimation of SED by PPAQ compared to the activity tracker [44]. The mean biases were 6.8, 7.2 and 8.1 hr/day, respectively, at baseline, GA week 28 and GA week 34. Hence, results from the two different methods are difficult to compare. Secondly, the PA dose in EXE was delivered with high fidelity [45]. This could influence EXE participants' perception of SED, thus subjectively reporting less SED in the PPAQ. Although combining various methods to measure SED during pregnancy gives a comprehensive assessment, rigorous studies are needed to gain better knowledge about SED during pregnancy.

***Validity of activity trackers for measuring total sleep time***

The validity of the Garmin Vivosport in measuring sleep during pregnancy has not been tested before. One study reviewed the validity of Garmin activity trackers, not including Garmin Vivosport, in measuring sleep and found that sleep time was overestimated by the activity trackers when using a sleep diary as a criterion method [46], which is in alignment with our data. Also, when using polysomnography as a criterion method, other brands of activity trackers tend to overestimate sleep time and underestimate wake time after sleep onset [46,47]. A recent study investigated the validity of three consumer activity trackers, including Garmin

Vivosport, in older adults and found that all three activity trackers had a high level of accuracy for measuring sleep time [48].

***Strengths and limitations***

PA behaviour during pregnancy is difficult to evaluate accurately. It is a strength that this study utilised both subjective and objective methods at different times during pregnancy. The activity tracker was advantageous to continuously capturing sleep time and SED throughout pregnancy. However, the consumer activity tracker's validity, adaptability, and applicability in research and clinical practice need standardisation and consensus [49]. The manufacturer processes the sleep and SED measures from the activity tracker, and the algorithms have not been published; for instance, how the activity tracker distinguishes between sitting, lying, and standing, or sleep stages, is proprietary information. Moreover, the inherited bias from self-reporting of sleep and SED from the questionnaires is inevitable. An additional limitation of this study is that the analysis is secondary; hence, no sample size nor power calculation was made on the outcomes of the present analyses.

## Conclusion

This study affirmed that pregnant women are prone to low sleep quality and high SED, which worsens as pregnancy progresses. Pregnant women who received structured supervised exercise training had better sleep quality and less SED than pregnant women receiving standard prenatal care when reported subjectively. When measured objectively by the consumer activity tracker, no differences were observed between groups. In an online setting, due to COVID-19 restrictions, SED was increased among pregnant women who received the EXE intervention. In conclusion, interventions that increase PA levels might improve sleep quality and decrease SED in pregnant women.

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**Authors' contribution**

B.S. initiated and directed FitMum. S.A.A., S.dP.K., C.B.R., J.M.B., T.D.C., S.M., E.L. and B.S. developed the study protocol. S.dP.K. and C.B.R. 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. S.A.A performed the activity tracker data management and performed statistical analyses. A.K.J. supervised the statistical analyses. J.E.L. contributed with expertise in self-tracking, and P.J. contributed with expertise in sleep medicine. S.A.A. drafted the manuscript, supervised by B.S., and all authors read, contributed, and approved the final version of the manuscript.

**Conflicts of Interest**

None

**Data Availability Statement**

Due to confidentiality, the datasets utilised in the current work are not publicly accessible. However, data are available upon justifiable request from the corresponding author, obtained the Danish Data Protection Authority's consent per the Data Protection Act, and finished a Standard Contractual Clause to ensure the transfer's legal basis.

**List of abbreviations**

CI: confidence intervals; CON: Standard care; COVID-19: coronavirus disease 2019; EXE: Structured supervised exercise training; GA: gestational age; MOT: Motivational counselling on physical activity; MVPA: Moderate-to-vigorous-intensity physical activity; PA: Physical activity; PSQI: Pittsburgh Sleep Quality Index; PPAQ: Pregnancy Physical Activity Questionnaire; RCT: Randomised controlled trial; SED: sedentary time; TST: total sleep time.

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