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Changes in mode of transportation to work or school from pre-pregnancy to early pregnancy in the Norwegian Fit for Delivery study

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ABSTRACT

Objective. To describe changes in mode of transportation to work or school from pre-pregnancy to early pregnancy, to describe levels of physical activity related to mode of transportation to work or school, and to examine associations between changes in mode of transportation to work or school and educational level, body mass index (BMI) and age.

Methods. Between September 2009 and February 2013, 575 healthy pregnant nulliparous women were included into the Norwegian Fit for Delivery (NFFD) trial. At inclusion they reported their current and their pre-pregnancy mode of transportation to work or school. Data were analysed by multilevel mixed models with dichotomized modes of transportation as dependent variables.

Results. There was a significant change towards less active transportation to work or school and a decrease in level of physical activity from pre-pregnancy to early pregnancy. Pre-pregnancy, 58% used private transportation to work or school, compared to 64% in early pregnancy (p=0.001). The percentage of women who biked (11% v. 5%, p<0.001) decreased significantly from pre-pregnancy to early pregnancy.

Conclusions. In this sample of Norwegian women there was a significant change towards less active transportation to work or school and lower levels of physical activity from pre-pregnancy to early pregnancy.

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Introduction

Active transportation is a feasible way to incorporate physical activity into daily life and has substantial public health (Laverty et al., 2013) and environmental benefits (Woodcock et al., 2009). Research has shown that people who use active modes of transportation (walking, biking and public transportation) to work increase their daily level of physical activity compared to those who use private transportation (Yang et al., 2012). Mode of transportation is influenced by underlying factors such as gender (Laverty et al., 2013; Millett et al., 2013; Panter et al., 2011; Pucher et al., 2010a), ethnicity (Laverty et al., 2013; Thern et al., 2015), age (Laverty et al., 2013; Millett et al., 2013; Saris et al., 2013), and level of education (Goodman et al., 2012; Laverty et al., 2013; Panter et al., 2011). Other important aspects are; distance from home to work (Goodman et al., 2012; Panter et al., 2011), convenience of public transportation (Wen et al., 2010), access to workplace car parking (Goodman et al., 2012; Wen et al., 2010) and travel safety (Bopp et al., 2014; Saris et al., 2013).

Women are more likely than men to walk (Laverty et al., 2013; Panter et al., 2011; Yang et al., 2012) or use public transportation (Laverty et al., 2013; Vagane L, 2009), but less likely to use private transportation or bike to work (Garrard et al., 2006; Laverty et al., 2013; Panter et al., 2011; Rissel et al., 2012; Yang et al., 2012). The gender difference in biking is however, not found in countries with an established culture for biking (Pucher et al., 2010a; Scheepers et al., 2013). Furthermore, female bikers are more concerned about safety (Garrard et al., 2006; Saris et al., 2013), and more sensitive to environmental and workplace support (Bopp et al., 2014) than men.

Low to moderate intensity levels of physical activity during pregnancy have several beneficial maternal health effects (Nascimento et al., 2012). Women who plan to get pregnant and pregnant women without any obstetric or medical complications are advised to undertake at least 30 min of moderate intensity physical activity a day on most, if not all, days of the week (ACOG Committee Opinion Number 267, 2002; Norwegian Directorate of Health, 2014). The majority of pregnant women do not meet these recommendations (Gaston and Cramp, 2011; Gjestland et al., 2013; Hegaard et al., 2011), and although there are few contraindications to moderate physical activity in pregnancy, reduction in the amount and level of physical activity is the norm

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from pre-pregnancy to pregnancy (Gaston and Cramp, 2011; Hegaard et al., 2011; Juhl et al., 2012; Liu et al., 2011; Owe et al., 2009; Pereira et al., 2007).

In many countries the employment rate among women is high making active transportation to work or school one way to integrate physical activity into pregnant women's day-to-day routine (WHO, 2002), thus making adherence easier (Das and Horton, 2012).

We aimed to describe pre-pregnant and early pregnant mode of transportation to work or school and changes in modes of transportation to work or school from pre-pregnancy to early pregnancy in a cohort of Norwegian nulliparous women, to examine associations between modes of transportation to work or school and level of physical activity, and to examine potential associations between change in modes of transportation to work or school and maternal education, BMI and age.

Methods

Population and study design

The present article is based on data from the NFFD randomised controlled trial (Sagedal et al., 2013). Nulliparous women were consecutively recruited from eight antenatal clinics around Kristiansand in Southern Norway from September 2009 to February 2013. Further inclusion criteria have previously been published (Sagedal et al., 2013). For the present study women who did not work or study prepregnancy or at inclusion were excluded.

Assessment of mode of transportation to work

At inclusion, in median gestational week 15.0 (range; 7.0–20.0 weeks), the women answered the questions; "How do you usually get to work/school now?" and in retrospect; "How did you usually get to work/school before pregnancy?" Respondents were asked to indicate which of the five listed transportation modes represented their main mode of travelling to work/school: "walk", "bike", "public transportation", "car" or "motorcycle/scooter/moped". It was only possible to select one main mode. Thus, information on multi-mode transportation was not captured. The two items; "car" and "motorcycle/scooter/moped" were pooled into one item labelled "private transportation". Modes of transportation were dichotomized into "walking" (=1) and "not walking" (=0), "biking" (=1) and "not biking (=0), "private transportation" (=1) and "not private transportation" (=0).

Based on data from a previous study (Overby et al., 2015) where pregnant women reported pre-pregnant and current mode of transportation to work or school 14 days apart, the test-retest agreement was 95% (88 out of 93) (kappa measure of agreement 0.80) and 89% (85 out of 95) (kappa measure of agreement 0.73) for pre-pregnant and current mode of transportation to work or school, respectively.

Other study variables

Pre-pregnant physical activity levels were assessed with the International Physical Activity Questionnaire short version (IPAQ-S) (2005). IPAQ-S assesses physical activity level in all arenas (leisure-time, occupation, house-hold and transport) the last seven days. MET (Metabolic Equivalent Task) score (MET-minutes ×week⁻¹) was calculated as outlined in the IPAQ manual (2005) for the last seven days. A questionnaire regarding lifestyle and background factors such as educational level and maternal age was filled in at inclusion. The response options on level of education were: < 7 years of primary education; 7–10 years of primary education; 11–12 year education; trade school or 1–2 years of high school; completed high school; <4 years at college/university and ≥4 years at college/university. Education was dichotomized into low education (not having attended

college or university) and high education (having attended college or university). Height was measured to the nearest centimetre (cm), using a Seca Leicester portable stadiometer with an accuracy of 0.1 cm. Weight prior to pregnancy was self-reported and used for calculation of prepregnancy BMI (weight/height²). According to the World Health Organization's definition of normal weight and overweight/obese (World Health Organization, 2000), we dichotomized: BMI $< 25 \ kg/m^2$ and BMI $\geq 25 \ kg/m^2$. Maternal age was dichotomized $< 25 \ years$ versus $\geq 25 \ years$.

Statistical methods

Maternal characteristics are presented as the mean \pm standard deviation (SD) for continuous variables and numbers and percentages for categorical variables. MET-scores are presented as mean and 95% confidence intervals (CIs). Chi-square statistics or Fisher's exact test were used when appropriate for comparison of categorical data. Oneway ANOVA and Tukey post hoc analysis or unpaired two-sided Student t-test were used to compare multiple or two groups, respectively. For repeated measures we used repeated measures ANOVA and Bonferroni post-hoc analysis. Mode of transportation and the changes in mode of transportation from pre-pregnancy to early pregnancy were analysed using a multilevel linear mixed model with dichotomized transportation variables as the dependent variables (Hellevik, 2009). According to the present literature, there might be a difference in pregnant women's modes of transportation depending on educational level, BMI and age (Evenson and Wen, 2011; Liu et al., 2011; Owe et al., 2009). Thus, the model included maternal educational level, BMI and age, as well as the following interaction terms: time \times maternal education, time \times BMI and time \times age to investigate potential differences in changes in the means of transportation from pre-pregnancy to median gestational week 15 between low and high maternal educational level, BMI and age. A significant effect was defined by a p value of the product term of less than 0.10. The analyses were performed with SPSS 22.0 (SPSS, Inc., Chicago, IL). Statistical analyses were conducted as twotailed tests with a 0.05 level of significance.

Results

The inclusion of 575 pregnant women was per protocol (Sagedal et al., 2013) (Fig. 1). There was no difference in pre-pregnant BMI or gestational age between included and excluded women, but the excluded women had a lower educational level (p < 0.001) and were younger (p = 0.020) than the included women.

Baseline characteristics

Baseline characteristics are described in Table 1. Mean maternal age at inclusion was 28.2 (SD 4.3) years, mean pre-pregnant BMI was 23.8 (SD 3.7) kg/m², and mean pre-pregnant MET-score was 2334 (SD 2011) MET-minutes \times week $^{-1}$.

Mode of transportation

Changes in the modes of transportation from pre-pregnancy to early pregnancy are presented in Fig. 2. The greatest change was seen among the women who reported to bike pre-pregnancy: only 46% continued to bike in early-pregnancy. A similar trend was seen among women who walked pre-pregnancy: 63% continued to walk. Among women who used public transport pre-pregnancy 81% continued with public-transportation, and almost all (97%) of those travelling with private transportation pre-pregnancy continued the same transportation in early pregnancy (Fig. 2). Three women reported driving motorcycle/scooter/moped both pre-pregnancy and in early pregnancy.

Private transportation was used by 58% pre-pregnancy, compared to 64% in early pregnancy (p = 0.001). The percentage of women who

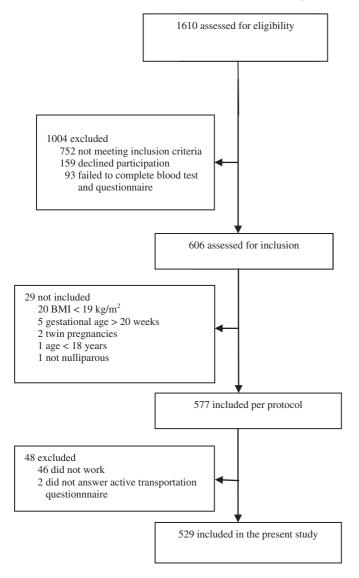


Fig. 1. Flow diagram of the inclusion of pregnant women in the Norwegian Fit for Delivery(NFFD) trial, September 2009 to February 2013.

biked (11% v. 5%, p < 0.001) decreased significantly from pre-pregnancy to early pregnancy (Table 2). Women with lower education increased their use of public transportation (25% v. 29%), compared to women with higher education (19% v. 18%; interaction time*education, p = 0.047). Furthermore, lower-educated women increased their use of private transportation (58% v. 61%) less than higher-educated women (57% v. 67%; interaction time × education, p = 0.069) (Table 2).

Physical activity level

Pre-pregnant and early pregnancy levels of physical activity were reported by 97% and 81%, respectively, and 80% reported their level of physical activity at both occasions. Physical activity levels among women who reported the same mode of transportation to work or school pre-pregnancy and in early pregnancy are presented in Table 3. There was a significant decrease in physical activity level from pre-pregnancy to early pregnancy (p < 0.001). The decrease in physical activity level did not differ between groups. Women who biked or walked to work or school reported higher level of physical activity than those who used public or private transportation, both pre-pregnancy and in early pregnancy, but the differences in physical activity between groups only reached significance in early pregnancy (p = 0.012). Furthermore,

Table 1 Sociodemographic characteristics at inclusion among healthy, pregnant, nulliparous women (N=529). Norwegian Fit for Delivery (NFFD) trial, September 2009 to February 2013

	n	%
Maternal age (years)		
<20	6	1.1
20-24	120	22.7
25–29	251	47.4
30-34	113	21.4
35+	39	7.4
Education ^a		
< 7 years	0	0.0
7–10 years	6	1.1
11-12 years	59	11.2
Completed high school	85	16.
<4 yrs college/university	181	34.2
≥4 yrs college/university	198	37.4
BMI (kg/m^2)		
19.0-<20.0 ^b	49	9.3
20.0-<25.0	323	61.1
25.0-<30.0	121	22.9
≥30.0	36	6.8
MET score ac		
<1000	137	25.9
1000-<2000	156	29.5
2000-<3000	108	20.4
3000-<4000	43	8.1
≥4000	84	15.9

- a (N = 528).
- $^{\rm b}$ Women had to have BMI $\geq 19.0~{\rm kg/m^2}$ to be included in the NFFD trial.
- ^c MET (Metabolic Equivalent Task) score (MET-minutes × week⁻¹).

those who continued biking in early pregnancy reported significant higher level of physical activity in early pregnancy than those who continued with private transportation (p = 0.034) (Table 3).

Discussion

The present study revealed that pre-pregnancy nearly six in ten women travelled by private transportation to work/school. There was a trend towards less active transportation in early pregnancy as fewer women biked and the use of private transportation increased. From pre-pregnancy to early pregnancy lower-educated women increased their use of public transportation significantly more than higher-educated women, and higher-educated women significantly increased their use of private transportation compared to lower-educated women. Furthermore, there was a significant decrease in physical activity from pre-pregnancy to early pregnancy irrespective of transport mode.

In line with most previous reports mainly from developed countries (Flint et al., 2014; Laverty et al., 2013; Lindstrom, 2008; Thern et al., 2015) private transportation was the main mode of transportation to work or school among women both pre-pregnancy and in early pregnancy. The dominance of private transportation in the present study might partly be explained by the fact that Norway has a high rate of car ownership (572 cars per 1000 population in 2013) (Statistics Norway, 2014c). In 2009, 85% of the Norwegian population lived in a household with at least one car and one in three households had two cars (Vagane L, 2009).

Earlier studies, have found that pregnant women bike less in early pregnancy compared to pre-pregnancy (Haakstad et al., 2007; Juhl et al., 2012; Owe et al., 2009). Biking might be considered more strenuous than walking, and pregnancy symptoms and concern about safety have been given as reasons for giving up biking in pregnancy (Evenson et al., 2009; Pereira et al., 2007; Sui et al., 2013).

The proportion of women in the present study who reported walking as their main mode of transportation to work or school was around

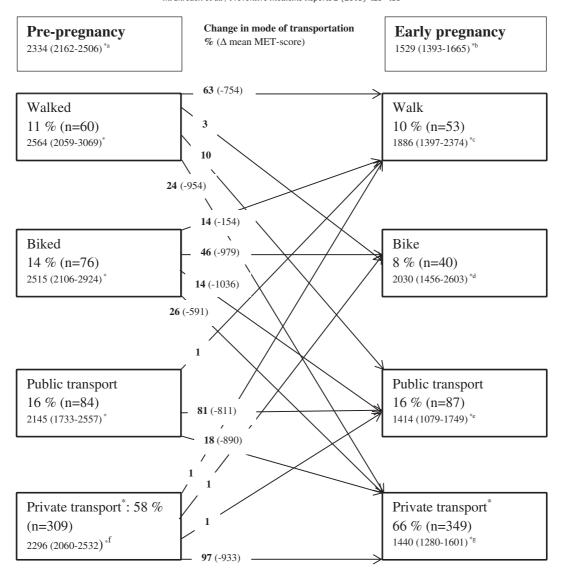


Fig. 2. Mode of transportation to school or work (% (n)) and corresponding MET (Metabolic Equivalent Task) score (MET-minutes \times week $^{-1}$) (mean (95%CI)) in the Norwegian Fit for Delivery (NFFD) trial, September 2009 to February 2013. Changes in mode of transportation from pre-pregnancy to early-pregnancy (%) and corresponding change (Δ) in mean MET score (MET-minutes \times week $^{-1}$). a n = 528, b n = 433, c n = 47, d n = 33, e n = 72, f n = 308, g n = 281.

10%, and did not change significantly from pre-pregnancy to early pregnancy. Walking is well tolerated and is the most common mode of physical activity in pregnancy (Haakstad et al., 2007; Liu et al., 2011; Owe et al., 2009). As walking at a moderate pace (5 km/h) is sufficient to meet the definition of moderate intensity activity, it has been promoted as the potentially most effective means to achieve the targeted daily physical activity recommendations. Furthermore, walking is convenient, familiar, free of charge and has been labelled a "near perfect exercise" (Morris and Hardman, 1997).

In accordance with other studies, biking and walking to work or school in the present study were more common among women with higher educational level (Panter et al., 2011; Rissel et al., 2014; Scheepers et al., 2013). The association between educational level and the use of active transportation to work varies depending on the population studied (Goodman et al., 2012; Laverty et al., 2013; Panter et al., 2011; Vagane L, 2009) One reason might be that higher educated people in some societies tend to live in areas with higher proximity to work, thus making active transportation more feasible (Goodman et al., 2012). In the present study women with higher educational level were more likely to convert to private transportation from prepregnancy to early pregnancy than women with lower educational

level. This might be partly explained by the fact that people with higher education are known to have better access to cars, and people who have access to cars travel less often with public transportation (Vagane L, 2009). In order to increase active transportation an integrated approach that includes restrictions on car use, changes of infrastructures, and active transportation programmes alongside education and awareness has been advocated (Pucher et al., 2010b).

A study from Oslo reported that 53% used private and 32% public transportation to work in third trimester of pregnancy (Haakstad et al., 2007). The greater use of public transportation and lower use of private car compared to the present study might be explained by a more urban setting with limited workplace parking and well developed public transport (Vagane L, 2009).

According to national Norwegian data for men and women combined, 66% used private car, 15% public transportation, 11% walked, 6% cycled, 1% used motorcycle/moped and 1% other transportation in their work journey in 2009. Women tended to use less private and more public transportation (Vagane L, 2009). Compared to national data, women in the present study travelled more often with bike and public transportation pre-pregnancy. Our results might reflect the infrastructure of the semi-urban area where the study was

Table 2 Changes in modes of transportation from pre-pregnancy to early pregnancy among pregnant, women (N = 529), Norwegian Fit for Delivery (NFFD) trial, September 2009 to February 2013. Data given as percentage (%) and 95% confidence interval (CI).

	Pre-pregnancy		Early pregnancy ^a		
	%	95%CI	%	95%CI	p-value
Walk	9.6	6.2-13.1	7.9	4.7-11.2	0.239*
Low education	8.0	2.8-13.2	5.5	0.6-10.4	
High education	11.3	7.1-15.5	10.3	6.4-14.3	0.568**
$BMI < 25 \text{ kg/m}^2$	9.3	5.5-13.1	9.4	5.8-13.0	
$BMI \ge 25 \text{ kg/m}^2$	10.0	4.8-15.2	6.4	1.5-11.4	0.154**
Age < 25 years	7.5	1.8-13.1	7.0	1.7-12.4	
Age ≥ 25 years	11.8	7.9-15.7	8.8	5.1-12.5	0.374**
Bike	10.7	6.9-14.5	4.7	1.8-7.5	< 0.001 *
Low education	8.7	3.0-14.4	3.8	-0.5-8.1	
High education	12.8	8.1-17.4	5.5	2.1-9.0	0.427**
$BMI < 25 \text{ kg/m}^2$	14.8	10.6-18.9	7.1	4.0-10.2	
BMI \geq 25 kg/m ²	6.7	0.9-12.4	2.3	-2.1-6.6	0.234**
Age < 25 years	8.6	2.4-14.8	1.8	-2.9-6.4	
Age ≥ 25 years	12.8	8.6-17.1	7.6	4.4-10.8	0.621**
Public transport	21.9	18.0-25.7	23.5	19.6-27.3	0.267*
Low education	25.1	19.3-30.9	29.3	23.5-35.1	
High education	18.7	14.0-23.4	17.6	12.9-22.7	0.047**
$BMI < 25 \text{ kg/m}^2$	21.7	17.4-25.9	22.4	18.1-26.7	
BMI \geq 25 kg/m ²	22.1	16.3-27.9	24.5	18.6-30.4	0.499**
Age < 25 years	30.6	24.2-36.9	31.2	24.8-37.6	
Age ≥ 25 years	13.2	8.9-17.6	15.7	11.3-20.1	0.519**
Private transport	57.8	52.4-63.1	63.9	58.8-69.1	0.001*
Low education	58.2	50.2-66.3	61.4	53.7-69.1	
High education	57.3	50.8-63.8	66.5	60.2-72.8	0.069**
$BMI < 25 \text{ kg/m}^2$	54.2	48.3-60.1	61.1	55.4-66.7	
BMI \geq 25 kg/m ²	61.3	53.2-69.4	66.8	59.1-74.6	0.666**
Age < 25 years	53.4	44.6-62.1	60.0	51.5-68.4	
Age ≥ 25 years	62.1	56.1-68.2	67.9	62.2-73.7	0.821**

BMI: body mass index.

- ^a Median gestational week 15.
- * P-value based on repeated measure model.
- ** P-value based on multilevel linear mixed model.

conducted. Kristiansand was ranked second in "the bike friendly city contest" in Norway in 2012 (Syklistenes landsforening, 2012), and has an offensive strategy on how to promote bicycling within the municipality (Kristiansand municipality, 2010).

The significant decrease in physical activity level from prepregnancy to early pregnancy is well documented in earlier studies (Fell et al., 2009; Gaston and Cramp, 2011; Hegaard et al., 2011; Juhl et al., 2012; Liu et al., 2011; Owe et al., 2009; Pereira et al., 2007). A Canadian cohort study reported the largest decrease in physical activity in early pregnancy to be in the domain of sports and exercise (Fell et al., 2009). Similarly, the decrease in physical activity level from prepregnancy to early pregnancy in the present study was independent of mode of transportation to work or school, indicating that the largest decrease in physical activity in early pregnancy might be in other domain of physical activity than active transportation.

Previous research also demonstrates that those who walk or bike to work have a higher level of physical activity compared to those who use private transportation (Yang et al., 2012). In accordance with this, we found that those who continued biking in early pregnancy reported significant higher level of physical activity than those who continued with private transportation.

Strengths and limitation

Major strengths of this study are the inclusion of women attending public healthcare clinics attended by most of the pregnant women in Norway as part of the national antenatal care programme, and the high response rate.

The study sample was confined to nulliparous women and was biased towards higher educated and older women. In Norway in 2011 48% of women aged 25–29 years had not attended university (Statistics Norway, 2014a), compared to 28% in the present sample. Mean age at inclusion in the present study was 28.2 years, whereas mean age of nulliparous women at delivery in Norway in 2011 was 27.7 years (Norwegian Institute of Public Health, 2013). Higher education is associated with increased use of active transportation (Goodman et al., 2012; Vagane L, 2009). Mixed findings have been reported on associations between age and transportation to work (Liu et al., 2011; Vagane L, 2009).

By excluding mothers who did not speak Norwegian or English, the NFFD study included few immigrant women. Pregnant immigrant women might have different travel habits (Thern et al., 2015) and different levels of physical activity (Berntsen et al., 2014; Gaston and Cramp, 2011) than the women in the present study. Furthermore, the study was restricted to nulliparous women. Women with children at home have better access to cars than women without children. Further they use private car more often than women without children, as their work/school trips might be more inclined to be connected with trips for other purposes such as shopping and transport to and from kindergarten (Vagane L, 2009). Moreover, an inverse association between having children and level of physical activity has been reported (Gaston and Cramp, 2011; Pereira et al., 2007).

The frequency of active commuting is likely to vary between regions. The present study was conducted in an urban/semi-urban setting in the municipality of Kristiansand and its neighbouring counties. Kristiansand municipality has a population of 85,000 inhabitants (Statistics Norway, 2014b). The quality of public transport measured by distance to bus stop or train station and departure frequency is good within the centre of the municipality, but service level is considerably poorer in the surrounding areas (Vagane L, 2009).

Other obvious limitations are the cross-sectional design and the reliance on self-reported data. The data on pre-pregnancy transportation and physical activity were collected in retrospect and thus we cannot rule out recall bias. There is no clear consensus on how to assess physical activity during pregnancy (Evenson et al., 2012). The IPAQ-S

Table 3Physical activity level* among women** who reported the same mode of transportation to work or school pre-pregnancy and in early pregnancy. Norwegian Fit for Delivery (NFFD) trial, September 2009 to February 2013.

Mode of transportation	Pre-pregnancy ^a	Early pregnancy bc	Change from pre-pregnancy to early pregnancy d	P value e
Walked-walk	2710 (1900-3519)	1956 (1263-2648)	-754(-1067441)	< 0.001
Biked-bike	3083 (2297-3869)	2104 (1502-2706)	-979(-1535424)	< 0.001
Public-public	2303 (1782-2824)	1491 (1072-1911)	-811(-1149474)	< 0.001
Private-private	2355 (2102-2608)	1422 (1244-1599)	-933(-1126-740)	< 0.001

^{*} MET (Metabolic Equivalent Task) score (MET-minutes × week⁻¹). Data given as mean (95% CI).

- ^a P value = 0.072.
- $^{\rm b}$ P value = 0.012.
- $^{\rm c}$ P value = 0.034 comparing "biked-bike" with "private-private".
- $^{\rm d}\,$ P value = 0.742. ANOVA and Tukey post hoc analysis
- ^e Comparing changes in MET-score from pre-pregnancy to early pregnancy. Repeated measures ANOVA and Bonferroni post-hoc analysis.

^{**} Based on women with valid MET scores pre-pregnancy and in early pregnancy. Numbers are: Walked-walk: n = 32, Bike-biked: n = 34, Public-public; n = 60, Private-private; n = 257.

has several limitations; it is not designed for use in pregnancy and might not be the most feasible tool to record physical activity related to active transportation (Harrison et al., 2011). The women who ended up participating in the NFFD might have been more health-conscious and more likely to adhere to a healthy lifestyle including a more active mode of transportation to work or school than the average pregnant woman. Factors which are known to predict mode of transportation to work or school, such as car access, distance to work and the departure frequency and distance to the bus or train, were not addressed. Symptoms associated with pregnancy such as nausea, heartburn, low back pain, weight gain and tiredness might have an impact on pregnant women's travel habits (Gaston and Cramp, 2011; Owe et al., 2009). Since we did not monitor these symptoms, we do not know if they had any influence on the observed changes in transportation behaviour.

Conclusion

There was a change towards less active transportation and lower physical activity level in early pregnancy compared to pre-pregnancy. High education was associated with a change towards more private and less public transportation in early pregnancy.

Sources of funding

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Contributions

LRS, IV, HL-S and EB conceived the NFFD study. MS, NCØ and EB designed the present study. MS drafted the rationale. LRS was responsible for the data collection. MS and EB carried out statistical procedures. MS drafted the paper. All the authors revised the paper critically.

Ethics

The study has been approved by the Norwegian Regional Committee for Medical Research Ethics South-East C (REK reference 2009/429). The Fit for Delivery trial has the Clinical Trials registration: clinicaltrial.gov NCT01001689. Written informed consent was obtained from all participants.

Conflicts of interest

The authors declare that they have no conflicts of interest.

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