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Original research

Evaluation of a blended care programme for caregivers and working pregnant women to prevent adverse pregnancy outcomes: an intervention study

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ABSTRACT

Objective Work-related activities can be a risk factor for pregnancy complications such as preterm birth. This study evaluates the effectiveness of a blended care programme, Pregnancy and Work, that provides pregnant workers and their obstetrical caregivers with advice on work adjustment.

Methods Women less than 20 weeks of gestation, in paid employment or self-employed, in the care of four participating hospitals and their referring midwifery practices in the Netherlands received either the blended care programme (n=119), consisting of a training for professionals and a mobile health application, or care as usual (n=122) in a controlled intervention study with a follow-up in intervention and control populations. All participants completed three questionnaires concerning health and working conditions at 16, 24 and 32 weeks of pregnancy. Primary outcome was the percentage of women who received advice from their obstetrical caregiver about work adjustment. Secondary outcomes were work status, realised work adjustment and working conditions. Groups were compared using univariate and multivariate regression analyses.

Results A total of 188 (78%) completed all three questionnaires. In the blended care group, women received more advice from obstetrical caregivers to adjust their work than in the control group, 41 (39%) vs 21 (18%) (adjusted relative risk (aRR) 2.2, 95% CI 1.4 to 3.4), but less from their employer 8 (8%) vs 31 (28%) (aRR 0.29, 95% CI 0.14 to 0.61). There were no significant differences in realised work adjustments. At 24 weeks, 30% of the pregnant women in both groups continued to work in hazardous workplaces.

Conclusion Among working pregnant women, the blended care intervention increases advice on work adjustment given by midwives and obstetricians, but does not lead to more work adjustments.

INTRODUCTION

Many women with a paid job continue working during their pregnancy. In the USA, more than 65% of pregnant women work while in the Netherlands, 9 in 10 women have a paid job and continue occupational activities during their first pregnancy.^{1 2} Exposure to certain working conditions during pregnancy is associated with adverse pregnancy outcomes (preterm birth, low birth weight,

Key messages

What is already known about this subject?

- Exposure to certain working conditions during pregnancy is associated with adverse pregnancy outcomes.
- Working pregnant women and their healthcare professionals are often unaware of these risks and of maternity protection legislation.
- Pregnant women continue to work in a hazardous workplace or decide to withdraw from work using sick leave or preventive pregnancy leave schemes.

What are the new findings?

- We developed a blended care programme called 'Pregnancy and Work', which consists of a training session for professionals and a mobile health application (the P&W app), to provide pregnant women and their obstetrical caregivers with personalised advice on work adjustment.
- Among working pregnant women, the blended care intervention increases advice on work adjustments given by midwives and obstetricians, but less from their employer, not leading to more work adjustments.
- Only a few employers inform their pregnant employees about rights and risks, despite there being a legal obligation to do so.
- At 24 weeks of pregnancy, almost a third of the women in both groups continued to work in hazardous workplaces.

fetal abnormalities) and pregnancy complications (hypertension, eclampsia, miscarriage).^{3–13} Many working pregnant women, their healthcare professionals and employers are unaware of these risks and legal measures concerning maternity protection in the workplace. In the European Union, including the Netherlands, employers are responsible for providing work adjustments to pregnant employees where necessary. However, due to a lack of implementation of the legislation, some of the pregnant women continue to work in a hazardous workplace or decide to withdraw from work using sick leave or preventive pregnancy leave schemes.^{14 15}

Key messages

How might this impact on policy or clinical practice in the foreseeable future?

- ▶ Improving the design of the P&W app for working pregnant women, obstetrical caregivers and employers could increase the effectiveness of the blended care 'Pregnancy and Work' intervention and lead to a safer workplace for pregnant employees.
- ▶ Obstetrical caregivers can play a role in advising pregnant women on topics related to their health in their working environment and work together with occupational physicians.
- ▶ To prevent adverse pregnancy outcomes, attention should be paid to safe working conditions earlier in pregnancy.

Providing pregnant women with information about the required work adjustment can encourage them to realise this in their own work and thus prevent the adverse effects of poor working conditions on pregnancy or withdrawal from work on sick leave. As women of childbearing age are frequent consumers of online health information,¹⁶ mobile health (mHealth) application, defined as the use of mobile devices for medical and public health practice,¹⁷ has the potential to serve as a practical source of information, provided that such information is understandable and well dosed, with a good interaction between app and user and meets existing guidelines.¹⁸ Although most mHealth lifestyle and medical apps for pregnant women seem to be feasible and acceptable, the evidence on effectiveness is limited, and most intervention studies have evaluated small study populations.¹⁹ An iterative multidisciplinary approach with involvement of end users from the start is important for the development of applications.²⁰

A stepwise approach was employed to develop an mHealth application, the Pregnancy and Work app (P&W app), based on the evidence-based guideline for occupational physicians: *Pregnancy, postpartum period and work*.²¹ This app provides pregnant workers, in paid employment or self-employed, with personalised advice to adjust their work, adapted to their individual working conditions and health. Prior studies providing content and design instructions for the development of the P&W app¹⁸ considered the app to be valuable and able to meet the needs of end users.²² All stakeholders (pregnant women, occupational physicians, general practitioners, midwives, obstetricians and representatives of trade unions and employers' organisations) were involved in the developmental process. Blending face-to-face guidance with online support improves client-therapist connection and adherence²³ and may increase the coverage, quality and efficiency of occupational and safety health education.²⁴ Successful examples are interactive e-learning modules such as that concerning occupational asthma for healthcare professionals which resulted in greater use and awareness of national occupational asthma guidelines.²⁵ Occupational hygiene e-courses for students were evaluated positively on effectiveness in a blended application.²⁶

Therefore, we developed the blended care 'Pregnancy and Work' programme, consisting of a training session for professionals and an mHealth application to provide pregnant women and their obstetrical caregivers with advice on work adjustment.

The aim of this study was to evaluate whether this blended care programme leads to more advice about work adjustment from obstetrical caregivers to their clients (1) and whether these

pregnant women realise more work adjustments than those receiving care as usual (2).

METHODS**Design**

We evaluated the effectiveness of the blended care P&W programme in a controlled intervention study with a follow-up study of the intervention and control populations.

In the Netherlands, prenatal care is supervised by midwives in primary care and by obstetricians in secondary care. Midwives take care of low-risk pregnancies. If specialised care is needed, midwives refer to an obstetrician in an affiliated hospital. We will refer to this stratified care model as a 'cluster', meaning a hospital including all surrounding midwifery practices.²⁷

Participating clusters were followed during two consecutive time periods. The first period covered January 2016 to April 2017, and the second period covered May 2017 to August 2018. Between the two time periods the training of healthcare professionals took place as part of the intervention. During the second time period patients were also offered the mobile phone (P&W) app. Selection of participants was not consecutive but depended on availability of a trained healthcare professional and the available time at the prenatal visit.

Participants

Women, >17 years, less than 20 weeks pregnant in paid employment or self-employed, and visiting one of 24 obstetric care facilities in four clusters in the North West region of the Netherlands were eligible for the study.

Intervention

The blended care programme consisted of a training session for midwives and obstetricians about the Netherlands Society of Occupational Medicine²¹ *Pregnancy, postpartum period and work* guidelines and the use of the P&W app. The training aimed to equip participants with the skills necessary to be able to work with the advice generated by the P&W app to guide their clients. After the training session, these midwives and obstetricians gave their clients access to the P&W app.

The P&W app (in Dutch and English) was developed as a web-based app, accessible from every type of mobile browser, with an adaptive design for desktop and mobile phone use. The content is based on the evidence-based guideline for occupational physicians and provides end users with personalised advice on possible work adjustments.²¹ The P&W app is described in more detail in our previous study²² and in online supplemental file A. The control group received care as usual.

Procedure

Obstetrical caregivers in participating clusters provided verbal and written study information to eligible clients. After digital informed consent was given women received access to the questionnaires and P&W app if applicable.

Obstetrical caregivers (midwives and obstetricians) of the four participating clusters started including for the control group from January 2016 to April 2017 (step 1). Between March and April 2017, obstetrical caregivers of the same four participating clusters followed a multidisciplinary training session together with occupational physicians.²¹ Subsequently, from May 2017 to August 2018, these obstetrical caregivers recruited participants for the intervention group (step 2). All participants received access to the online questionnaires at 16, 24 and 32 weeks of pregnancy. Some participants completed the questionnaire after

receiving a reminder, which was sent 2–3 weeks after the first request. Participants in the intervention group received access to the P&W app after registration.

Outcome measurements

The primary outcome was the percentage of pregnant women who received advice about their work from their midwife or obstetrician. Secondary outcomes were work status (still at work or on sick leave), work advice (from whom) and complaints of health and pregnancy, realised work adjustments and working conditions. The intervention was considered effective if pregnant women in the intervention group received advice statistically significantly more often from their midwife or obstetrician to adjust their work and realised work adjustments in their work more often than women in the control group.

Data collection

All participants (both control and intervention groups) received emails to complete three different online questionnaires at 16, 24 and 32 weeks of pregnancy. The first questionnaire included baseline characteristics such as data on educational level, general health and lifestyle, and medical problems in current and former pregnancies. In addition, questions from a validated questionnaire about psychosocial job strain and physically demanding work⁷ supplemented with questions about other working conditions (eg, (irregular) working times, and chemical, biological and physical factors (noise, climate)) were used. To determine the influence of private factors on the health and work capacity of pregnant women, the last part of the questionnaire concerned commuting, sports and household characteristics. The questionnaires at 24 and 32 weeks of pregnancy concerned work status (normal working hours, sick leave or pregnancy leave), working conditions, health complaints and (advice on/realised) work adjustment, and leisure and household characteristics in the second and third trimesters. Sick leave was defined as (permitted) absence from work because of illness. We distinguished two types of leave in the period granted to mothers in connection with pregnancy and childbirth: pregnancy leave (prior to childbirth) and maternity leave (after childbirth). Data were collected on web-based electronic case report forms and were stored in anonymised form in a database.

Statistical analysis

General descriptive statistics are given for baseline characteristics as frequencies with percentages, means with SD or medians with IQRs.

Tests of univariate analyses were χ^2 or Fisher's exact tests, the Mann-Whitney tests or t-tests. Multivariate models for adjusted analysis were done using generalised linear models, with log link and binomial distribution to estimate adjusted relative risks (aRR).²⁸ RR estimates for received advices to adjust work and for achieved work adjustments were adjusted for those variables which differed significantly between intervention and control groups: working conditions concerning job strain and information from employer about work adjustment when reporting pregnancy.

Outcomes on changes in work at 24 and 32 weeks of pregnancy were analysed as cumulative changes (any changes during follow-up). Therefore, these outcomes represent data that were analysed without the use of a mixed model or generalised estimating equations. Effects of hierarchical clustering of intervention effects or heterogeneity of outcomes due to hierarchical ordering of data (ie, centre effects) were assessed using cluster

Table 1 Results of multidisciplinary training session for healthcare providers on NVAB 'Pregnancy, postpartum period and work' guidelines and P&W app

| Characteristics of participants | 90 (100%) | |
|--|------------|----------------|
| Profession | | |
| Midwife | 47 (53%) | |
| Obstetrician | 10 (11%) | |
| Occupational physician | 32 (36%) | |
| Work experience (years) | | |
| <10 | 20 (22%) | |
| 10–25 | 35 (39%) | |
| >25 | 35 (39%) | |
| Knew about the NVAB 'Pregnancy, postpartum period and work' guideline | | |
| No | 27 (30%) | |
| Yes | 25 (28%) | |
| Yes and uses it | 36 (40%) | |
| The training | | |
| | Yes | Neutral |
| The training was valuable to me. | 88 (98%) | 1 (2%) |
| The training is in line with my knowledge. | 83 (92%) | 7 (8%) |
| I will recommend the app to my patients. | 85 (94%) | 5 (6%) |
| I'm going to use the P&W app. | 78 (87%) | 12 (13%) |

All variables mentioned as n (%).

NVAB, Netherlands Society of Occupational Medicine; P&W app, Pregnancy and Work app.

analysis, as well as by stratification of outcomes by centre, with visual and statistical assessment. A cut-off value for statistical significance for heterogeneity was not prespecified as the limited sample size was considered to preclude formal statistical inference. Data were analysed using IBM SPSS Statistics V.24.0.

RESULTS

A total of 57 obstetrical caregivers employed at one of the four participating clusters, together with 32 occupational physicians, followed one of the four multidisciplinary training sessions on the guideline and the use of P&W app (table 1). Most of the participants rated the training as valuable (98%, n=88) and would recommend the app to their patients (94%, n=85) and use it (87%, n=78).

A total of 241 women were included in the study: 122 in the control group and 119 in the intervention group. Of this number, 188 (78%) women completed all three questionnaires: 101 in the control group and 87 in the intervention group. Online supplemental file B shows the study flow chart.

Baseline characteristics, demographics, education, general health, and general working and private conditions were comparable in both groups (table 2). A large majority of participating women were Caucasian and well educated.

The primary outcome, the percentage of women receiving advice from their midwife or obstetrician to adjust their work, was 9% in the intervention group vs 2% in the control group at 16 weeks of pregnancy (RR 5.64), and 39% vs 18% at 24 weeks of pregnancy (RR 2.18) (table 3).

The secondary outcome concerning work status shows that there were no significant differences at 16 and 24 weeks of pregnancy between both groups (table 3). From 32 weeks of pregnancy, significantly fewer participants in the intervention group were on pregnancy leave (RR 0.42). During pregnancy, the participants in both groups reported an increasing number of complaints due to pregnancy, which restricted them in their work: more than 30% at 16 weeks, around 40% at 24 weeks and around 50% at 32 weeks of pregnancy (table 3).

Table 3 shows that among pregnancy women in the 'in employment' group (ie, excluding participants who were self-employed),

Table 2 Baseline characteristics of pregnant workers participating in the study, in control and intervention groups at 16 weeks of pregnancy*

| Variable | Intervention group n=119 | Control group n=122 | P value |
|--|-----------------------------|------------------------|---------|
| Demographics and general health | | | |
| Age (years)† | 32 (5) | 33 (4) | 0.251 |
| Ethnic origin: Caucasian‡ | 102 (86%) | 110 (90%) | 0.288 |
| Educational level | | | |
| University education or higher academic education | 69 (58%) | 68 (56%) | Ref |
| Higher professional education | 35 (29%) | 33 (27%) | 0.881 |
| Senior secondary vocational education | 15 (13%) | 21 (17%) | 0.354 |
| Body mass index (kg/m ²) >25 | 22 (19%) | 14 (12%) | 0.172 |
| Health complaints/chronic illness before pregnancy | 10 (8%) | 10 (8%) | 0.954 |
| Medication prescribed by physician | 18 (15%) | 17 (14%) | 0.480 |
| Smoking during pregnancy | 0 | 2 (2%) | 0.498 |
| Drinking alcohol during pregnancy | 4 (3%) | 2 (2%) | 0.442 |
| Drugs: quit before pregnancy or earlier | 21 (18%) | 14 (12%) | 0.174 |
| Current pregnancy | | | |
| With a fertility treatment | 9 (8%) | 9 (7%) | 0.985 |
| Twins or triplet | 3 (3%) | 4 (3%) | 1.000 |
| Parity ≥1 | 52 (44%) | 62 (51%) | 0.268 |
| Medical problems in former pregnancies? | 9/52 (17%) | 12/62 (19%) | 0.532 |
| Medical problems before current pregnancy? | 10 (8%) | 10 (8%) | 0.954 |
| Increase in complaints because of current pregnancy? | 37 (31%) | 39 (32%) | 0.884 |
| Work | | | |
| Paid work from start of the pregnancy | 119 (100%) | 122 (100%) | 1.000 |
| Employment sector | | | |
| Healthcare | 34 (29%) | 32 (26%) | Ref |
| Business services and research | 31 (26%) | 37 (30%) | 0.473 |
| Education, welfare and child care | 20 (17%) | 18 (15%) | 0.913 |
| Retail and hospitality and catering industry | 14 (12%) | 16 (13%) | 0.660 |
| Government and culture, recreation | 13 (11%) | 11 (9%) | 0.823 |
| Other (industry/NGOs/transport) | 6 (5%) | 8 (7%) | 0.756 |
| Number of employees in the company >50 | 81 (68%) | 85 (70%) | 0.715 |
| Self-employed§ | 6/105 (6%) | 8/117 (7%) | 0.615 |
| Commuting: travel distance >10 km | 71 (60%) | 73 (59%) | 0.980 |
| Travel time >1 hour/day (min/hour) | 50 (42%) | 49 (40%) | 0.768 |
| Private conditions | | | |
| Sport | 66 (56%) | 57 (47%) | 0.195 |
| Times spent on hobby spending >5 hours/week | 9 (8%) | 9 (7%) | 0.985 |
| Children (living at home): Yes | 41 (35%) | 48 (39%) | 0.375 |
| Housework largely done by participant herself | 23 (19%) | 22 (18%) | 0.820 |

*Complete results in online supplemental file C.
 †Mean (SD), all other variables mentioned as n (%).
 ‡Non-Caucasian includes: Turkish, Moroccan, Afro/American, Asian, Mixed and 'other non-Western'.
 §Based on second questionnaire (not in first questionnaire).
 NGO, non-governmental organisation; NS, not significant; Ref, reference.

participants in the intervention group received information from their employer, when reporting pregnancy, significantly less often at 24 weeks (RR 0.55) and at 32 weeks of pregnancy (RR 0.41). This difference concerned advice on the required work adjustments: 6% in the intervention group vs 18% in the control group at 24 weeks, 6% vs 21% at 32 weeks, and on pregnancy and maternity leave (14% vs 30%) at 32 weeks.

At 16, 24 and 32 weeks of pregnancy there is a consistent, although not significant trend of difference in realised work

adjustments, 14% vs 18%, 21% vs 32% and 37 vs 45%, respectively (table 3). In both groups, pregnant women adjusted mostly physically demanding work (less standing and walking, lifting and carrying) and working hours (fewer hours and night shifts). Both groups also worked from home more often.

Intervention and control groups were comparable in most working conditions (table 4). Before 20 weeks of pregnancy, participants in the intervention group experienced less pressure at work (RR 0.55) and had less need to slow down (RR 0.62). They enjoyed their work less often (RR 0.86) and were less often satisfied with their work (RR 0.84). After 24 weeks of pregnancy, participants in the intervention group experienced less freedom in performing tasks (RR 0.57). They enjoyed their work less often (RR 0.34) and were less often satisfied with their work (RR 0.37).

At 24 weeks of pregnancy, about 30% of the pregnant workers, whether in paid employment or self-employed, reported physically demanding work and exposure to biological agents and noise. Of the respondents, 16% reported 'physically very demanding work'.

Table 5 shows that, when adjusted for the working conditions in which both groups differed significantly, women in the intervention group more often received advice from their midwife and/or obstetrician (aRR 2.22), but less often advice and/or information from their employer (aRR 0.29). Although at 24 weeks of pregnancy, the frequency of realised work adjustments was higher in the control than in the intervention group, these differences were not significant, nor when adjusted for the variables in which the intervention and control groups differed significantly (working conditions concerning job strain and information about the required work adjustments the employee received from employer when she reports being pregnant). Analyses for hierarchical clustering of data for participating centres, or heterogeneity of intervention effects on the primary outcomes did not indicate centre effects.

DISCUSSION

This study shows that pregnant women, either in paid employment or self-employed, received more frequently advice from their obstetrical caregiver to adjust their work after a blended care intervention. However, they received less often advice and/or information from their employer. Although at 16, 24 and 32 weeks of pregnancy, the frequency of realised work adjustments was higher in the control than in the intervention group, these differences were not significant. At 24 weeks of pregnancy, almost a third of the pregnant women in both groups continued to work in hazardous workplaces.

Considering the long-term consequences of pregnancy complications such as preterm birth and low birth weight, awareness of work-associated risk factors is important and can have a substantial effect on the health of the offspring and on medical costs associated with complications. This study investigated the added value of a relatively cheap blended care intervention of training of obstetrical professionals, subsequent counselling of women as well as the mHealth application ('app' for short) with easily accessible reliable information about pregnancy and work to achieve higher levels of work adjustment during pregnancy. We have carefully developed and tested this mHealth application (the *P&W* app). The app allows all working women participating in the study, whether in employment or self-employed, to determine work and personal risk factors and to adjust their work according to the recommendations given in the app. When designing mHealth applications, an iterative approach

Table 3 Pregnant workers' work status, work advice and adjustments at 16, 24 and 32 weeks of pregnancy*

| | 16 weeks of pregnancy | | | | | | 24 weeks of pregnancy | | | | | | 32 weeks of pregnancy | | | | | | |
|--|-----------------------------|-------------|------------------------|--------------|-------|----------|-----------------------------|--------------|------------------------|-------|----------|-------------|----------------------------|--|------------------------|--|----|--|--|
| | Intervention group n=119 | | Control group n=122 | | RR | | Intervention group n=105 | | Control group n=117 | | RR | | Intervention group n=87 | | Control group n=101 | | RR | | |
| | | | | | | | | | | | | | | | | | | | |
| Current work status | | | | | | | | | | | | | | | | | | | |
| Normal working hours | 118 (99%)† | 122 (100%)† | | Ref | | | 89 (85%) | 100 (86%) | | | | 59 (68%) | 56 (55%) | | | | | | |
| Part time due to illness | 1 (1%)† | 0† | | 0.897 | | | 8 (8%) | 8 (7%) | | | | 8 (9%) | 9 (9%) | | | | | | |
| No work due to illness | 0 | 0 | | | | | 7 (7%) | 5 (4%) | | | | 11 (13%) | 10 (10%) | | | | | | |
| Pregnancy leave | 0 | 0 | | | | | 1 (1%) | 4 (3%) | | | | 9 (10%) | 26 (26%) | | | | | | |
| Increase complaints | 37 (31%) | 39 (32%) | | 0.884 | | | 44 (42%) | 45 (39%) | | | | 52 (52%) | 42 (42%) | | | | | | |
| Information from employer when reporting pregnancy | | | | | | | | | | | | | | | | | | | |
| Yes‡ | NA | NA | | | | | 17/99 (17%) | 34/117 (31%) | | | | 12/84 (14%) | 33/98 (35%) | | | | | | |
| Information about‡ | | | | | | | | | | | | | | | | | | | |
| Work adjustments | NA | NA | | | | | 6/99 (6%) | 20/117 (18%) | | | | 5/87 (6%) | 20/101 (21%) | | | | | | |
| Pregnancy/maternity leave | NA | NA | | | | | 16/99 (16%) | 27/117 (25%) | | | | 12/87 (14%) | 28/101 (30%) | | | | | | |
| Advice to adjust work from | | | | | | | | | | | | | | | | | | | |
| Midwife and obstetrician | 11 (9%) | 2 (2%) | 5.64 | 1.28 to 24.9 | 0.010 | 41 (39%) | 21 (18%) | 2.18 | 1.38 to 3.43 | 0.001 | 36 (41%) | 29 (29%) | | | | | | | |
| Occupational physician | 2 (2%) | 0 | | 0.243 | | 6 (6%) | 11 (9%) | | | | 11 (13%) | 12 (12%) | | | | | | | |
| Manager or staff advisor | 2 (2%) | 6 (5%) | | 0.281 | | 6 (6%) | 14 (12%) | | | | 10 (11%) | 17 (17%) | | | | | | | |
| Own initiative | 11 (9%) | 16 (13%) | | 0.498 | | 21 (20%) | 30 (26%) | | | | 31 (36%) | 29 (29%) | | | | | | | |
| Realised work adjustments | 17 (14%) | 22 (18%) | | 0.430 | | 22 (21%) | 37 (32%) | | | | 32 (37%) | 45 (45%) | | | | | | | |
| Less physically demanding | 4 (3%) | 7 (6%) | | 0.377 | | 2 (2%) | 9 (8%) | | | | 10 (12%) | 13 (13%) | | | | | | | |
| Less standing or walking | 4 (3%) | 9 (7%) | | 0.168 | | 6 (6%) | 6 (5%) | | | | 11 (13%) | 11 (11%) | | | | | | | |
| Fewer hours/day | 5 (4%) | 6 (5%) | | 0.726 | | 8 (8%) | 12 (10%) | | | | 19 (22%) | 15 (15%) | | | | | | | |
| More working from home | 5 (4%) | 7 (6%) | | 0.524 | | 3 (3%) | 10 (9%) | | | | 8 (9%) | 10 (10%) | | | | | | | |

*Complete results in online supplemental file C.

†At start of pregnancy.

‡Self-employed participants excluded: 24 weeks n=13 (6%), 32 weeks n=10 (5%).

NA, not applicable, not in questionnaire 1 (16 weeks of pregnancy); RR, relative risk.

Table 4 Working conditions from pregnant workers at 16 and 24 weeks of pregnancy*

| | 16 weeks of pregnancy | | | | | 24 weeks of pregnancy | | | | |
|---------------------------------------|--------------------------|---------------------|------|--------------|---------|-------------------------|---------------------|------|--------------|---------|
| | Intervention group n=119 | Control group n=122 | RR | 95% CI | P value | Intervention group n=97 | Control group n=108 | RR | 95% CI | P value |
| Working times | | | | | | | | | | |
| Hours/week† | 34.4 (7.4) (6–50) | 33.4 (9.1) (8–50) | | | 0.382 | 33.6 (8.6) (4–48) | 32.1 (9.5) (6–60) | | | 0.590 |
| Days/week† | 4.3 (0.8) (2–6) | 4.1 (1) (1–7) | | | 0.184 | 4.4 (0.1) (0–6) | 4.2 (0.8) (0–6) | | | 0.400 |
| Irregular working times | | | | | | | | | | |
| Evening shifts‡ | 17 (14%) | 18 (15%) | | | 0.897 | 12 (12%) | 17 (16%) | | | 0.489 |
| Night shifts‡ | 17 (12.4) (10.6) | 17 (6.7) (12.3) | | | 0.902 | 11 (22.3) (3.2) | 14 (19.9) (2.2) | | | 0.723 |
| | 18 (9) (7.5) | 18 (3) (6.3) | | | 0.957 | 2 (2.2) (1.9) | 4 (2.7) (1.5) | | | 0.686 |
| Physical work | | | | | | | | | | |
| Standing/walking ≥4 hours/day | 37 (32%) | 41 (35%) | | | 0.678 | 32 (32%) | 33 (34%) | | | 0.833 |
| Lifting/carrying loads or people | 33 (28%) | 31 (25%) | | | 0.712 | 18 (19%) | 20 (19%) | | | 0.994 |
| Physical work: regularly/often | | | | | | | | | | |
| Bending | 28 (24%) | 25 (21%) | | | 0.592 | 19 (20%) | 26 (24%) | | | 0.438 |
| Physically very demanding | 24 (19%) | 17 (14%) | | | 0.351 | 15 (16%) | 17 (16%) | | | 0.957 |
| Requiring physical strength | 19 (16%) | 14 (12%) | | | 0.323 | 14 (14%) | 10 (9%) | | | 0.250 |
| Job strain: often/always | | | | | | | | | | |
| Problems with pressure | 17 (14%) | 32 (26%) | 0.55 | 0.32 to 0.91 | 0.021 | 11 (11%) | 17 (16%) | | | 0.360 |
| Like to take things a little easier | 23 (19%) | 38 (31%) | 0.62 | 0.40 to 0.98 | 0.035 | 23 (24%) | 28 (26%) | | | 0.714 |
| Freedom in performance of tasks | 83 (70%) | 93 (76%) | | | 0.257 | 61 (63%) | 85 (79%) | 0.57 | 0.37 to 0.90 | 0.013 |
| Influence on the pace to work | 57 (48%) | 67 (55%) | | | 0.303 | 50 (52%) | 60 (58%) | | | 0.359 |
| Planning own work | 75 (63%) | 77 (63%) | | | 0.975 | 59 (61%) | 70 (65%) | | | 0.555 |
| Support from manager | 66 (56%) | 80 (66%) | | | 0.091 | 55 (57%) | 67 (62%) | | | 0.437 |
| Enjoy working | 93 (78%) | 111 (91%) | 0.86 | 0.77 to 0.96 | 0.006 | 76 (79%) | 100 (93%) | 0.34 | 0.16 to 0.74 | 0.003 |
| Finds work satisfying | 93 (78%) | 113 (93%) | 0.84 | 0.76 to 0.94 | 0.001 | 73 (75%) | 98 (91%) | 0.37 | 0.19 to 0.74 | 0.003 |
| Exposed to biological agents | 36 (30%) | 33 (27%) | | | 0.610 | 24 (35%) | 29 (27%) | | | 0.200 |
| Exposed to chemical agents | 9 (8%) | 7 (6%) | | | 0.581 | 9 (9%) | 7 (7%) | | | 0.456 |
| Noise | 40 (34%) | 32 (26%) | | | 0.226 | 32 (33%) | 31 (29%) | | | 0.507 |

*Complete results in online supplemental file C.

†Mean (SD) (min-max).

‡n, mean hours/week (SD), all other variables mentioned as n (%).

RR, relative risk.

is important to meet the needs of end users.²⁰ The application under study was designed by a multidisciplinary team. During the development phase, all stakeholders were involved in focus groups and a usability study was performed.^{18 22} In addition, women received advice from their obstetrical caregiver (midwives, obstetricians), who followed a multidisciplinary training session, as part of the intervention.

Previous studies have shown the importance of using text messaging or interactive and individual coaching to improve the

lifestyles of pregnant women.^{16 29} Blending face-to-face guidance with online support is more effective and increases client-therapist connection and adherence.^{23 24} In this study, we combined individual access to the P&W app with counselling by professionals trained to work with the advice generated by the app, thus extending the already personalised advice provided by regular emails with updated work advice during pregnancy. Obstetrical caregivers have little awareness of the guidelines, risks and legal measures concerning maternity protection.¹⁴ By providing

Table 5 Advice/information to adjust work and realised work adjustments n=222, 24 weeks of pregnancy, multivariable analysis

| | Intervention group n=105 | Control group n=107 | Univariate analysis | | | Multivariate analysis | | |
|--|--------------------------|---------------------|---------------------|--------------|---------|-----------------------|--------------|---------|
| | | | RR | 95% CI | P value | aRR* | 95% CI | P value |
| Advice/information to adjust work | | | | | | | | |
| From midwife and/or obstetrician (advice to adjust work) | 41 (39%) | 21 (18%) | 2.18 | 1.38 to 3.43 | 0.001 | 2.22 | 1.44 to 3.43 | 0.000 |
| From employer (advice to adjust work and/or information about work adjustments when reporting pregnancy) | 8 (8%) | 31 (28%) | 0.28 | 0.14 to 0.59 | 0.001 | 0.29 | 0.14 to 0.61 | 0.001 |
| | | | RR | 95% CI | P value | aRR† | 95% CI | P value |
| Realised work adjustments because of pregnancy | 22 (21%) | 37 (32%) | 0.66 | 0.42 to 1.05 | 0.078 | 0.66 | 0.41 to 1.08 | 0.101 |

All variables mentioned as n (%)

*Association with working conditions: like to take things a little easier, enjoy work, work satisfying.

†Association with working conditions: like to take things a little easier, enjoy work, work satisfying and information from employer about work adjustment when reporting pregnancy.

aRR, adjusted relative risk; RR, relative risk.

midwives and obstetricians with easily accessible information, we expected them to better inform pregnant workers about the risks at work.

Data were prospectively collected at several times during pregnancy, as the working capacity of pregnant women changes over time. This allowed for longitudinal follow-up by which we could assess changes during the course of pregnancy.

The intervention and control groups were comparable in baseline characteristics and the differences in working conditions are few, but stable over time: the control group reported enjoying their job more commonly, this group also reported more freedom in performing their job, though with more working pressure. The lack of differences shown between the populations in terms of working times, and physical, biological and chemical working conditions, excludes a potential for confounding bias stemming from these conditions.

In our study, however, there may have been selection bias due to differences in participants in the intervention group compared with the control group. Women in the intervention group received significantly less information about the necessary work adjustment from their employers when they reported their pregnancy. Possibly this lack motivated them to participate in the study, in order to receive information about work adjustment via the P&W app. A limitation of our study is that we have no information on how many women in both groups were on temporary employment. Women with a temporary contract are at a much higher risk of pregnancy discrimination. In the Netherlands, almost half (49%) of all women with a temporary contract were not renewed or converted to a permanent contract because of their pregnancy or new motherhood.³⁰ They are reluctant to report their pregnancy to their employer.

Furthermore, compared with the general population there seems to be an over-representation in both intervention and control groups of highly educated, Caucasian, non-smoking women with low intake of alcohol during pregnancy. Compared with the baseline characteristics of a recently published large randomised controlled trial (n=13.520) in a low-risk pregnancy population in the Netherlands, the incidence of Caucasian ethnicity and high education were comparable.³¹ However, body mass index, alcohol consumption and smoking were lower in our cohort. This might be explained by the phenomenon that the decision to participate in a study can correlate with social, educational and health conditions.³² In our study, this may be related to the demographics of the participating practices, to language issues or availability of electronic devices in certain populations and even with selection by the obstetrical caregiver. However, as these baseline characteristics were comparable in both groups we do not expect this had an effect on the primary and secondary outcomes of our study.

Although the professionals are trained and the app provides personalised advice based on individual work-related and health-related risks, it is uncertain whether the advice that clients received from their obstetrical caregiver was correct and also whether the pregnant women adjusted their work adequately. Another limitation of this study is the number of lost to follow-up after the second questionnaire: only 78% of the participants completed all three questionnaires, possibly due to tiredness as a result of progressing pregnancy or completing work before starting pregnancy leave. However, because 92% of the participants completed the second questionnaire, we have insight in the (adjustments of) the working conditions of pregnant women up to the third trimester (28 weeks), that is, during the longest period of pregnancy for which pregnant Dutch women continue to work (up to 34 weeks).

Because this study uses three large questionnaires, multiple testing is involved, with the risk of false significance. However, the primary outcome measures, which are the most important results, have p values <0.01 or 0.001 suggesting a low risk of a type I error.

The finding that the intervention population has fewer pregnant workers on pregnancy leave in the period of 32 weeks of pregnancy could be a positive result, indicating more/better contact between obstetrical caregivers and workers on work adjustments in the intervention population (24 weeks), which prevented a number of pregnant workers from withdrawing from work using pregnancy leave. Another explanation may be that the employer provided information on maternity leave more often at 32 weeks.

The low score given to advice offered by occupational physicians in both groups is remarkable. National guidelines advise employers to give all their pregnant employees access to a preventive consultation with the occupational physician; however, in practice, this seems to happen less frequently than expected.

Our study has similarities with a stepped-wedge approach.³³ Due to the effect of the intervention, randomisation at the individual level is not possible: the effect is not limited to individuals. Midwives and obstetricians can share information and knowledge from the training session and P&W app with other healthcare providers and clients. Clients can share information from the P&W app with other pregnant women. Furthermore, the intracluster correlation was anticipated to be high: the clients of midwifery hospital partnerships can differ in ethnicity and social economic status, depending on, for example, location. The study design leaves larger uncertainty about non-causal reasons for the observed treatment effects than that of an individually randomised trial. Differences in patient characteristics and their baseline prognosis between the two treatment periods have, however, been adjusted for in the multivariable analyses. Nonetheless, structural residual confounding due to unobserved factors remains possible. A larger number of patients and a full stepped-wedge or cluster randomised design would be needed to account for such effects. Such large-scale study, however, was not feasible at this stage. Finally, the intervention motivated the professionals to participate in the study; thus, a stepped introduction of the intervention would ensure that all participating professionals and their future clients would benefit from the training session and P&W app.

In the European Union, including the Netherlands, according to Council Directive 92/85/EEC it is the employer's responsibility to evaluate the potential risks facing pregnant employees and to subsequently take the necessary protective measures. Lack of knowledge about legal obligations of employers can cause deficiencies in the implementation of maternity protection legislation. Often no risk analysis is carried out and employers fail to give pregnant workers sufficient information about their rights and risks.^{14 15} A negative attitude of employers towards their pregnancy is one of the most common stressors among working women.³⁴ Moreover, in our study fewer than 25% of the employers provided information to their pregnant employees about their rights, and only 12% about risks and required work adjustments even though this is a legal obligation. We do not know whether employers were aware of this legal obligation or the fact that less exposure to risks at work will reduce absenteeism among pregnant employees.^{35 36}

Working pregnant women, both in paid employment and self-employed, are often unaware of the risks and legal measures concerning maternity protection in the workplace, they continue to work in a hazardous workplace or decide to withdraw from

work using sick leave or preventive pregnancy leave.^{14 37} This study shows that overall work is not sufficiently adjusted: after 24 weeks of pregnancy, 20%–30% of the participants in both groups still performed physically demanding work (prolonged standing (33%), lifting (19%), bending (22%)), they worked in an environment with a lot of noise (30%), or on which was cold (18%), hot (18%) or entailed exposure to chemicals (7%) and infectious diseases (26%). The question remains whether there has been a proper evaluation of the working conditions of these pregnant women.

In future research, it is essential to include employers, more participants with lower education and non-Caucasian ethnicity, and information about temporary or permanent employment of participants. It is important to redesign the P&W app to meet the needs of different user groups: employers, their employees and caregivers. We expect that interaction in multidisciplinary training on the P&W app for caregivers and employers will encourage employers to pay more attention to (the working conditions of) their pregnant employees and use the advice from the P&W app to adjust the workplace.^{38 39} A follow-up study can evaluate whether the advice clients have received from their caregiver was correct and whether the pregnant women have adjusted their work adequately. In addition, government support is important to achieve better and more effective implementation of legislation concerning working conditions during pregnancy.²⁴ A comprehensive follow-up study focusing on health outcomes can demonstrate whether this blended care programme, including pregnant workers, obstetrical caregivers and employers, is effective in preventing adverse pregnancy outcomes.

CONCLUSION

The results of our study show that a blended care intervention, which consists of a training session for obstetrical caregivers and the personalised advice provided by a specifically developed mHealth application, increases the percentage of advices on work adjustments given by midwives and obstetricians to pregnant workers, but they received less often advice from their employer. However, it did not lead to more work adjustment. Improving the design of the P&W app, by including employers in its development, could increase the effectiveness of the intervention.

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