Power 4 a Healthy Pregnancy-intervention: the impact on empowerment and diet quality of pregnant women

Published: 24-09-2021
Last updated: 15-05-2024

The objective of the study is to measure the impact of the P4HP intervention on the empowerment and diet quality of pregnant women.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Lifestyle issues
Study type	Interventional

Summary

ID

NL-OMON49912

Source
ToetsingOnline

Brief title
Power 4 a Healthy Pregnancy-intervention

Condition

- Lifestyle issues

Synonym
Nutrition and empowerment

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: ZonMw,Regiodeal Foodvalley

Intervention

Keyword: diet quality, empowerment, pregnancy

Outcome measures

Primary outcome

The primary research variables are empowerment and diet quality.

Secondary outcome

The secondary research variables are sense of coherence, quality of life and

self-rated health.

Study description

Background summary

A healthy diet during pregnancy is crucial for the health of both mother and child. However, pregnant women often do not meet the nutritional requirements due to several challenges. Pregnancy, however, is a unique transition in which women are more receptive to changing dietary patterns compared to other phases in life. Nutrition promotion by midwives is promising to make use of this window of opportunity. Although midwives feel the responsibility to provide nutritional advice, they encounter barriers in providing nutrition communication. As a result, nutrition communication in antenatal care generally remains suboptimal. Empowerment is an important concept in midwifery care since midwives use their expertise to empower pregnant women to help them tackle health issues. This project implements and evaluates the P4HP-intervention, created for and with pregnant women to improve their diet quality. In this intervention, we use an empowerment approach because empowering pregnant women to improve their diet quality is expected to improve their health, as they are supported to make healthy choices. This intervention will contribute to enduring newborns with a healthy, successful start of life and has the potential to improve health across generations.

Study objective

The objective of the study is to measure the impact of the P4HP intervention on the empowerment and diet quality of pregnant women.

Study design

The research will be conducted in the form of a cluster randomized trial. Each participating midwifery practice is randomly assigned to the intervention or control group and thus forms one cluster. All participants in a midwifery practice are therefore in either the intervention or control group. It is possible within a practice to guide participants for individual consultations and participants for CP consultations. Due to practical reasons and possible bias, it is not possible to blindly conduct this study for the healthcare professionals, participants and researchers involved.

The P4HP intervention differs from standard maternity care by discussing the topic of nutrition at multiple moments during pregnancy with an empowering approach, with the aim of improving diet quality during pregnancy. As the intervention is embedded in a practice's processes and is different within each midwifery practice and population dependent, the P4HP intervention is designed to provide flexibility and customization. Involved professionals have the freedom to adapt to what the individual or group needs during each session. The researchers will discuss the best course of action with each participating practice to ensure that the intervention protocol is followed as closely as possible.

Intervention

The participants in the intervention group have a consult about nutrition with the midwife or dietician at 4 moments during pregnancy. No specific diet or behavioral change is imposed on the pregnant woman.

The first meeting with the midwife takes place at the beginning of the pregnancy around 8-10 weeks of the pregnancy. This conversation is about the context of the pregnant woman's diet. For example, it is discussed what the pregnant woman herself thinks is going well in terms of nutrition, what is important to her, what she would like to change, and where she sees opportunities for improvement.

The second conversation about nutrition takes place with the dietician, around 12 weeks of the pregnancy. As a nutrition expert, the dietitian can go deeper into what the pregnant woman encounters, such as nausea or fatigue. Here too, the specific situation of a pregnant woman and what she herself finds important is central. This consult lasts 30-45 minutes.

At around 22 weeks and 32 weeks, the pregnant woman reflects with the midwife about nutrition in the past weeks. They discuss what helped to eat healthier, what was difficult, and how the pregnant woman can deal with this in the future. The midwife supports the pregnant woman in coming up with solutions and options that suit her and her capabilities.

Pregnant women who follow CenteringPregnancy (CP) can also participate in this study. In that case, the discussions with the midwife and dietician take place in groups. The intake also takes place individually at CP. The first moment with the midwife is therefore identical to the individual trajectory.

The second conversation about nutrition, which takes place with the dietitian, is embedded in the first CP group meeting. During this meeting, 90 minutes are reserved to discuss nutrition and lifestyle during pregnancy and to set goals. Together with the midwife, the dietitian facilitates working methods in which women discuss what they encounter and what options there are for dealing with challenges related to food during pregnancy. Learning from each other and contact with fellow sufferers are an additional empowering factor in this process. However, it is less easy for the dietitian to deal with individual situations in a group setting.

The reflection moments can be incorporated in the third CP meeting (20-24 weeks) and the seventh CP meeting (30-34 weeks). The topics discussed in these meetings, such as breastfeeding and the first days after birth, invite reflection on the diet of the pregnant woman to be integrated.

Study burden and risks

There are no risks associated with participating in the study. Regular birth care is also not endangered. The burden of the research will be kept as low as possible, for example by integrating the intervention into regular consultations. The only burden the study entails is the time investment for the questionnaires at the start and the end of the study.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Inclusion criteria

In the first trimester of pregnancy; >=18 years old; able to understand and speak the Dutch language; a diet in which one hot meal is consumed per day

Exclusion criteria

Unwilling to sign informed consent; a condition/condition that affects dietary intake; a serious (chronic) disease or condition such as cancer

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-11-2021
Enrollment:	350
Type:	Actual

Ethics review

Approved WMO Date:	24-09-2021
Application type:	First submission
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 23191
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL78194.041.21
Other	NL9551
OMON	NL-OMON23191