# The effect of planned home visits made to the mothers with premature babies after hospital-discharge upon their postpartum depression, adaptation to motherhood role and newborns health

Submission date	<b>Recruitment status</b> No longer recruiting	<ul><li>Prospectively registered</li></ul>	
01/07/2013		Protocol	
Registration date	Overall study status Completed  Condition category Pregnancy and Childbirth	Statistical analysis plan	
11/07/2013		Results	
Last Edited		Individual participant data	
12/07/2013		<ul><li>Record updated in last year</li></ul>	

#### Plain English summary of protocol

Background and study aims

Birth before completing 37 weeks of pregnancy is called preterm labor and these babies are called as premature babies. Premature babies may have risk of many health problems and complications because their organs and systems are less developed than those of full term babies. Today, one out of ten births results in preterm labor and majority of these babies do not survive longer the initial days of live their life. Therefore, care of the premature babies that is performed during their early days at the hospital and at home after hospital-discharge, is very important. Besides, it is reported that mothers with premature babies experience such psychological problems and worry more compared to those mothers who give birth to full term babies. Therefore, those mothers with premature babies should be supported on baby care through home visits after hospital-discharge in order to prevent possible health problems to the baby, to maintain good mother-baby relationship during this period and to decrease psychological problems. Research reports that home visits paid during early days after hospital-discharge offer many advantages in terms of mother and baby health. But, research on home care after child birth is very scarce. This study was conducted in order to find out how well planned home visits paid to the mothers with premature babies after hospital-discharge works.

#### Who can participate?

Mothers who gave birth before the 37th week of the pregnancy at the Corum State Hospital between the January 2011 and the June 2011.

#### What does the study involve?

Participants were randomly allocated to either intervention group or to control group. Women belonging to the intervention group received training during their stay in the hospital and when

they got discharged, they were given consultation based on a handbook. The researcher visited them at home 4 times during their early days after discharge where they were given training and consultation about baby care. The control group did not receive any training.

What are the possible benefits and risks of participating?

Benefits include training about the newborn health, mothers and the babies health problem could be identified early, participants are directed to a health institution for the treating these problems. There is no risk of participating in the study as the methods are not invasive.

Where is the study run from?

The study was performed at the intensive care unit of the newborn, Corum State Hospital, Turkey.

When is the study starting and how long is it expected to run for? The study started in January 2011 and ended in May 2011.

Who is funding the study?
This study is funded by the investigator.

Who is the main contact?
Dr Nuriye Buyukkayaci Duman nurfatihh@hotmail.com

#### Contact information

#### Type(s)

Scientific

#### Contact name

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#### Additional identifiers

EudraCT/CTIS number

**IRAS** number

ClinicalTrials.gov number

**Secondary identifying numbers** N/A

# Study information

#### Scientific Title

The effect of planned home visits made to the mothers with premature babies after hospital-discharge upon their postpartum depression, adaptation to motherhood role and newborns health: a semi-experimental case-control study

#### **Study objectives**

Hypothesis of the research

H 1.Home visits paid to mothers with premature babies after hospital-discharge may have a decreasing effect upon mean postpartum depression scores.

H 2.Home visits paid to mothers with premature babies after hospital-discharge may have a positive effect upon adaptation to motherhood role.

H 3. Home visits paid to mothers with premature babies after hospital-discharge may have a decreasing effect upon health problems of the newborn.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Ethical Committee of Medical Faculty of Erciyes University with approval number of 2011/233

#### Study design

Semi-experimental case-control study

#### Primary study design

Interventional

#### Secondary study design

Case-control study

#### Study setting(s)

Hospital

#### Study type(s)

Quality of life

#### Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

#### Health condition(s) or problem(s) studied

Postpartum depression, adaptation to motherhood role and newborns health (nutritional problems, respiratory distress syndrome, anemia)

#### Interventions

Women in the intervention group and control group were at the Intensive Care Unit of Newborn of Corum State Hospital. After all patients were informed of the purpose the study and their oral consents were obtained; both groups were given Descriptive Data Collection Form about mothers and their babies characteristics. The researcher provided training for the women in the intervention group during the period when they were treated at the hospital and while they were being discharged from the hospital, they were given consultation about baby care

according to the handbook The Care of the Newborn Baby. The researcher did not provide the women in the control group with nursing intervention of any kind. After hospital-discharge (on the 7th day, 14th day, 28th day and 42nd day after birth), women in the intervention group were seen at their homes by the researcher. They were telephoned before the home visits and appointments were made and visit-day and hours were fixed. During each home visit, the researcher provided women in the intervention group with training about baby care according to the handbook and gave them consultation related to mothers needs. During the final home visit on the 42nd day after birth, women were given the Form to determine the Newborns Problems, Form of Adaptation to Motherhood Role (in order to determine mothers adaptation to motherhood) and Beck Depression Inventory (BDI) (in order to determine mothers postpartum depression).

#### **Intervention Type**

Other

#### Phase

Not Applicable

#### Primary outcome measure

1. The Form to determine the Newborns Problems:

There are three questions in the form about the health problems of the newborn, status of visiting the health institution and the reasons for visiting the health institution during the sixweek post-partum period after hospital-discharge in order to determine the problems experienced by the premature babies.

2. Form of Adaptation to Motherhood Role:

The form included two questions to inquire the problems experienced by mothers and babies in terms of the mother-baby relation and to explore the mothers adaptational status during the six week period.

3. Beck Depression Inventory (BDI):

BDI, developed by Beck et al. (1960), is one of the most used inventories in clinics and researches and can be administered for individuals aged between 13 and 80[19]. The inventory is consisted of 21 statements and is used to objectively measure the degree of depression and physical, emotional, mental and motivational symptoms seen during depression. The Turkish adaptation of the inventory was performed by Hisli (1988) and its validity and reliability coefficients are rather good[20]. It was found out that test-retest reliability coefficient was 0.65 and split-half reliability coefficient was 0.78 for students and 0.61 for depressive patients. Scores for the statements of the inventory range from 0 to 3. All of the scores are added and depression score is obtained. The highest score of the inventory is 63 (21 x 3). A higher total score means a higher level or severity of depression. Scores obtained from the inventory can be evaluated as follows: Score Evaluation

0-9 Normal

10-15 Slight depression

16-23 Moderate depression

24-63 Severe depression

#### Secondary outcome measures

Descriptive Data Collection Form about Mothers and their babies Characteristics
The form includes a total of 16 questions in order to explore both demographic characteristics
(such as age, educational status, monthly total income, etc.) and descriptive characteristics
related to the mothers and their babies (such as parity, total gestational weeks, birth weight of
the baby, state of breastfeeding and feeding the baby with supplement food, supplement food

or foods eaten by the baby, problems experienced by the baby during early postpartum period and hospital-discharge time).

#### Overall study start date

01/01/2011

#### Completion date

01/05/2011

## **Eligibility**

#### Key inclusion criteria

Women who lived in the city center of Corum, gave birth before the 37th gestational week and accepted to participate in the research voluntarily were included in the research.

#### Participant type(s)

**Patient** 

#### Age group

Adult

#### Sex

Female

#### Target number of participants

60

#### Key exclusion criteria

Those women and/or their babies who developed complications (mothers: postpartum hemorrhage, infection, etc.; babies: respiratory distress syndrome, intraventricular hemorrhage, necrotizing enterocolitis, neonatal asphyxia, etc.) and the women who had chronic diseases (heart diseases, hypertension, diabetes, renal diseases) were excluded from the study due to the idea that they may be affecting the results of the study.

#### Date of first enrolment

01/01/2011

#### Date of final enrolment

01/05/2011

#### Locations

#### Countries of recruitment

Türkiye

# Study participating centre Hitit University School of Health Corum

# Sponsor information

#### Organisation

Hitit University (Turkey)

#### Sponsor details

c/o Nuriye Büyükkayacý Duman School of Health Corum Türkiye 19030 nurfatihh@hotmail.com

#### Sponsor type

University/education

#### **ROR**

https://ror.org/00g212534

# Funder(s)

#### Funder type

Other

#### **Funder Name**

Investigator initiated and funded (Turkey)

## **Results and Publications**

#### Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

Not provided at time of registration