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Health After Birth Trial: using self-help to promote health in women after birth

Submission date
10/09/2013

Recruitment status
No longer recruiting

Registration date
10/09/2013

Overall study status
Completed

Last Edited
08/10/2018

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
We are looking at self-help interventions that can improve womens health after they have had a baby. Getting people to regularly write about stress or difficulties is a simple, low-risk intervention that has been shown to improve psychological and physical health in many groups of people. Although writing interventions may be helpful to women after birth, this has not been tried or tested. We have therefore developed a self-help writing intervention for new mothers. A previous small study showed women find it acceptable and helpful but we now need to test it to see whether writing does actually improve women's psychological and physical health.

Who can participate?
You are eligible to take part if you are over 18 years of age, have given birth in the previous six weeks, and your baby was born after the 26th week of pregnancy.

What does the study involve?
If you decide to take part, you will be randomly allocated to one of three groups. Everyone in these groups will be asked to fill in a questionnaire at three time points: at the beginning of the study, one month later and six months later. Most of you will also be asked to engage in a simple writing exercise where you write for at least 15 minutes every day for three days. The writing task either involves writing about (1) the event or difficulty that has been most stressful and upsetting since having the baby; or (2) a familiar room of your choice. The questionnaires will ask you about your psychological well-being, physical health, and your use of health services. You will be sent text message reminders when you need to complete the writing exercises or the questionnaires. We will also collect some information about the birth of your baby from your medical records.

What are the possible benefits and risks of participating?
We anticipate women who do the writing exercise will have some health benefits but cannot be sure until the completion of the study. If the self-help intervention is effective, it can immediately be provided to all women after birth via the internet. It will therefore provide immediate access to an easy self-help intervention to improve health in postnatal women. There are no foreseeable risks. However, some people might find that completing the study raises feelings or issues that they would like to talk about. If you find completing the booklet

distressing you can contact us on [HABIT tel: 020 7040 5864] or the NCT Helpline, a large UK charity supporting parents (tel. 0300 330 0700).

Where is the study run from?
The study is led by Professor Susan Ayers at City University London, in collaboration with Brighton and Sussex University Hospitals and the East Sussex Healthcare NHS Trust (UK).

When is the study starting and how long is it expected to run for?
The study is expected to start sending out initial information to new mums in October 2013, and then to start asking ladies to take part from the beginning of December 2013. We will be looking for new mums to take part for up to 10 months. This will allow us to finish collecting and analysing information by the middle of 2014.

Who is funding the study?
National Institute of Health Research (NIHR) (UK)

Who is the main contact?
Prof. Susan Ayers
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Contact information

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Scientific

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Additional identifiers

Protocol serial number
14390

Study information

Scientific Title
Using expressive writing interventions to promote health in women after birth: a randomised controlled trial

Acronym
HABIT

Study objectives
Giving birth is an important life event that raises specific challenges such as adjusting to the demands of a new baby.

Whilst this is usually a positive time, some women develop psychological problems such as depression or anxiety that have profound negative effects on them and their families.

Improving postnatal health is therefore a priority. NHS guidelines state that improving the health and welfare of mothers and their children is the surest way to a healthier nation and emphasise the need for postnatal intervention.

Getting people to regularly write about their thoughts and feelings (expressive writing) is a simple, low-risk and inexpensive intervention that in several groups has been shown to improve health and quality of life.

Although expressive writing interventions may be helpful to women after birth this has not been tried or tested. We have therefore developed an expressive writing intervention for new mothers following a feasibility study showing that the majority of women find expressive writing acceptable and helpful. It now needs to be tested to see whether expressive writing can actually improve women's psychological and physical health, quality of life and reduce healthcare service use.

This will be done by recruiting new mothers and randomly allocating them to one of three groups: an expressive writing group (writing their thoughts and feelings about stressful or difficult issues during or after birth), a control intervention group (writing about a familiar room), or normal care. The results of this study could have substantial benefits for the postnatal care provided by the NHS.

If expressive writing is effective, this research will provide immediate access to a cost-effective intervention that improves health in postnatal women, and which can be accessed directly by women via the internet. This can be made available immediately, both locally and nationally.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London Riverside, First MREC approval date 25/01/2013, ref: 12/LO/1753

Primary study design
Interventional

Study design
Randomised interventional prevention trial

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Topic: Mental Health Research Network, Reproductive Health and Childbirth; Subtopic: Anxiety, Depression, Reproductive Health and Childbirth (all Subtopics); Disease: Depression, Anxiety, Reproductive Health & Childbirth

Interventions
366 women divided between three conditions. Women consenting to participate will be randomised on a 1:1:1 ratio.

1. Expressive writing group (writing their thoughts and feelings about stressful or difficult issues during or after birth) - Expressive writing on three days during a one week period.
2. A control intervention group (writing about a familiar room)
3. Normal care.

Women complete a baseline questionnaire, the intervention and then have a subsequent questionnaire 1 month post-intervention and 6 months post-intervention.

Total duration of follow-up: 6 months.

Study Entry : Single Randomisation only

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Psychological/physical health and QoL; Timepoint(s): 1 month and 6 months post intervention

Key secondary outcome(s)
1. Acceptability of expressive writing to postnatal women; Timepoint(s): 6 months post intervention (women randomised to writing groups only)
2. Changes in healthcare service use; Timepoint(s): 1 month and 6 months post intervention

Completion date
19/06/2015

Eligibility

Key inclusion criteria
Women will be eligible for the study if they are over the age of 18 and have given birth after 26 weeks gestation within the previous 6 weeks

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Female

Key exclusion criteria
Women will be excluded if their baby is stillborn or dies before discharge from hospital

Date of first enrolment
01/11/2013

Date of final enrolment
01/12/2014

Locations

Countries of recruitment
United Kingdom

Study participating centre
Brighton and Sussex University Hospitals NHS Trust
United Kingdom
-

Study participating centre
Mid Staffordshire NHS Foundation Trust
United Kingdom
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Study participating centre
Southport & Ormskirk Hospital NHS Trust
United Kingdom
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Study participating centre
Harrogate and District NHS Foundation Trust
United Kingdom
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Study participating centre
Lancashire Teaching Hospitals NHS Foundation Trust
United Kingdom
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Study participating centre
Western Sussex Hospitals NHS Trust
United Kingdom
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Study participating centre
Surrey and Sussex Healthcare NHS Trust
United Kingdom
-

Study participating centre
St Helens and Knowsley Teaching Hospitals NHS Trust
United Kingdom
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Study participating centre
University Hospital Southampton NHS Foundation Trust
United Kingdom
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Study participating centre
Kettering General Hospital NHS Foundation Trust
United Kingdom
-

Study participating centre
North Tees & Hartlepool NHS Foundation Trust
United Kingdom
-

Sponsor information

Organisation
Brighton and Sussex University Hospitals NHS Trust (UK)

Funder(s)

Funder type
Government

Funder Name
NIHR Research for Patient Benefit (RfPB); Grant Codes: PB-PG-0211-24096

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	27/03/2018		Yes	No
Results article	results	01/10/2018		Yes	No
HRA research summary			28/06/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes