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Acceptability and effectiveness of multi-media delivery of an exercise programme among postpartum women with lumbo pelvic pain in Taiwan

Submission date
02/03/2016

Recruitment status
No longer recruiting

Registration date
29/04/2016

Overall study status
Completed

Last Edited
19/01/2018

Condition category
Signs and Symptoms

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

Plain English summary of protocol

Background and study aims
Lumbo Pelvic Pain (LPP) is a common problem among pregnant women and those that have given birth within the last year (postnatal). LPP may lead to sleep problems, depression, fatigue and anxiety, and a general inability to carry out activities that involve carrying or lifting. Various treatments have been used to reduce LPP in general including physical exercise although the effect of exercise programmes in treating back pain is yet to be fully understood among postnatal women. In any case, new mothers in many Asian countries, such as Taiwan, tend to reduce physical activity after birth in accordance with traditional practices. Mothers in Taiwan receive verbal advice on exercise to be followed in the postnatal period by health care professionals before their discharge from hospital. Most of the hospitals also provide the women with a leaflet containing details of an exercise programme to manage postpartum LPP commonly referred to as back pain. However, very little is known about the uptake of this exercise programme or its benefits for postnatal women. Technology has been increasingly used in health care to deliver various treatments and technology based delivery can improve the uptake of exercise among certain groups. How acceptable different methods of teaching the exercises, using digital or print media are and how they might affect how many postnatal women take up the exercise, adhere to it and complete an exercise programme has yet to be understood. Taiwan has a world-leading position in technology with 80% of all households owning personal computers and around 84% households with high speed internet connection. This study assesses the effectiveness of an exercise programme (the intervention) designed to strengthen abdominal and global muscles delivered using Digital Versatile Disc (DVD), Internet or leaflet, on LPP among postnatal women in Taiwan, and to compare exercise uptake, adherence and completion rates.

Who can participate?
Adult women (over 18) who are pregnant with their first baby (between 34-41 weeks gestation) and with LPP that was not present before they became pregnant

What does the study involve?
Participants are randomly allocated to one of two intervention groups (DVD or Internet) or the control group (leaflet). Following the birth of their child, all participants are given the same exercise programme. The exercise program is developed for strengthening core abdominal and global muscles through abdominal muscle exercises, breathing exercises, head and neck exercises and leg exercises. The DVD group are given the exercise programme on a DVD. The Internet group are given access to YouTube videos playing the same content as the DVD. The leaflet group are given a description of the exercise programme in the form of a printed leaflet. All participants are asked to report on the severity of their LPP after three days, six weeks and finally 4 months after having given birth.

What are the possible benefits and risks of participating?
Expected benefits are a reduction in LPP pain and an improvement in the quality of life in the postnatal period. There may also be benefits for the healthcare system as decreased back pain and improved quality of life might result in fewer return visits to health services. The study will provide valuable information about the use of electronic means of delivery for health care interventions for women. This information can be used for the implementation of related future initiatives, not only in Taiwan but also globally.

Where is the study run from?
Shin Kong Medical Centre Hospital, Taipei (Taiwan)

When is study starting and how long is it expected to run for?
November 2014 to October 2016

Who is funding the study?
University of Bedfordshire (UK)

Who is the main contact?
1. Ms Pei-Ching Tseng (public)
2. Dr Shuby Puthussery (scientific)

Contact information

Type(s)
Public

Contact name
Dr Shuby Puthussery

ORCID ID
http://orcid.org/0000-0002-1865-9546

Contact details
University of Bedfordshire
Putteridge Bury
Hitchin Road
Luton
United Kingdom
LU2 8LE

Type(s)
Public

Contact name
Mrs Pei-Ching Tseng

Contact details
University of Bedfordshire
Putteridge Bury
Hitchin Road
Luton
United Kingdom
LU2 8LE

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomised controlled trial to test the acceptability and effectiveness of multi-media delivery of an exercise programme among postpartum women with lumbo pelvic pain in Taiwan

Study objectives
This study aims to assess the effectiveness of an exercise programme delivered using Digital Versatile Disc (DVD), Internet or leaflet, on LPP among postnatal women in Taiwan, and to compare exercise uptake, adherence and completion rate across three modes of delivery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Shin Kong Medical Centre Hospital Ethics Committee, Taiwan, 11/12/2014, ref: 20141005R
2. Institute for Health Research Ethics Committee at the University of Bedfordshire, 05/02/2015, ref: IHREC452

Study design
Pragmatic prospective single-blinded randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Lumbo pelvic pain (LPP)

Interventions
The intervention comprises of an exercise programme, designed to strengthen core abdominal and global muscles, recommended for postnatal women in Taiwan delivered through digital (DVD or Internet) or print (leaflet) media. The exercise program is designed to strengthen core abdominal and global muscles through abdominal muscle exercises, breathing exercises, head and neck exercises and leg exercises. The program consist of eight components intended to perform at various time points following birth. Women were instructed to perform the exercises twice a day for 30 minutes with outcomes measured at baseline, six weeks and four months follow-up.

Women are randomly assigned into two intervention groups (DVD and Internet) and a control group (leaflet). Women in the DVD-based group received the exercise program in a DVD along with narrations and demonstrations of the programme. The content of the DVD was posted on YouTube and women in the Internet group were provided with instructions on locating the video link on YouTube. Women in the control group received standard postnatal care which included the customary information given by their nurses along with the leaflet. All the participant women receive the same verbal instructions from the research midwife.

Intervention Type
Other

Primary outcome measure
LPP measured using the Visual Analogue Scale (VAS) at 3 days, 6 weeks and 4 months postpartum

Secondary outcome measures
1. Physical endurance measured using the Disability Rating Index (DRI)
2. Changes in core muscles, determined by physical examinations including measurements of waist circumference, body weight, and diastasis recti performed by a trained research midwife
3. Uptake
4. Adherence
5. Completion rate of exercise

Uptake, adherence and completion rate of exercise is using the self-record sheet. A self-record sheet is given to all the participants to record daily exercise frequency, duration and method of

exercise. The record sheet also provided space to record reasons if not the exercise components were not followed as instructed.

All measured 3 days, 6 weeks and 4 months postpartum

Overall study start date
01/11/2014

Completion date
31/10/2016

Eligibility

Key inclusion criteria
1. Pregnant women who had LPP in the region of the lower back and/or anterior and/or posterior region of the pelvis and pain intensity on visual analogue scale (VAS) via self-report point on or over 30mm in the past week
2. Age > 18 years
3. Primipara and single-foetal pregnancy
4. No history of LPP before pregnancy
5. No history of perinatal complications for mother and baby
6. Planned vaginal delivery
7. Willing to provide informed consent for participation
8. Able to complete written forms in Mandarin

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
240

Key exclusion criteria
1. History of clinician-reported contraindications for exercise
2. History of diagnosis of spinal problems before pregnancy
3. History of LPP before pregnancy
4. Pain intensity on visual analogue scale (VAS) via self-report point less than 30mm in the past week
5. History of perinatal complications
6. Birth (planned/actual) by caesarean section
7. Age < 18 years

Date of first enrolment
01/03/2015

Date of final enrolment
30/08/2016

Locations

Countries of recruitment
Taiwan

Study participating centre
Shin Kong Wu Ho-Su Memorial Hospital
No. 95, Wenchang Rd
Shilin District
Taipei City
Taiwan
111

Sponsor information

Organisation
University of Bedfordshire

Sponsor details
University Square
Luton
England
United Kingdom
LU1 3JU

Sponsor type
University/education

ROR
https://ror.org/0400avk24

Funder(s)

Funder type
University/education

Funder Name
University of Bedfordshire

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The trialists will disseminate the trial protocol and the findings in peer reviewed journals and presentations at relevant conferences.

Intention to publish date
30/04/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Pei-Ching Tseng and Shuby Puthussery. Data is available currently until the end of 2018. Data will be shared for any further analysis jointly agreed with the trial authors for academics, practitioners and researchers. Participant consent has been obtained for anoynmised sharing for research-related purposes.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		13/10/2017	19/01/2018	No	No