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Evaluating the impact of sling provision and training upon maternal mental health

Submission date
12/01/2023

Recruitment status
No longer recruiting

Registration date
24/01/2023

Overall study status
Completed

Last Edited
13/11/2023

Condition category
Mental and Behavioural Disorders

✓ Retrospectively registered
✓ Protocol added
? SAP not yet added
✓ Results added
? Raw data not yet added
✓ Study completed

Plain English Summary
Background and aims
This study aimed to examine whether providing new mothers with an infant carrier ('sling') and training in how to use it, would lead to mothers having lower postnatal depression symptoms, compared to not being provided with an infant carrier and associated training.

Who can participate?
Expectant mothers

What does the study involve?
Participation involves completing a questionnaire within 6 weeks of the birth of their baby, and subsequently being randomly allocated to receive the sling plus training intervention either as soon as was convenient after randomisation, or after a wait period of 3 months. Participants then either received the intervention or were added to the waiting list to receive the intervention after 3 months. Participants completed questionnaires 6 and 12 weeks after the first questionnaire.

What are the possible benefits and risks of participating?
Direct benefits of this study include free sling hire where normally a charge would apply. While there may be no other immediate benefits for those participating in this study, it is hoped that this work will help improve our understanding of the impact of sling use on maternal mental health, well-being and parenting, and will inform future studies on this topic. The only disadvantage anticipated for taking part in this study is the time taken to complete the questionnaires. Otherwise, it is not anticipated that participating in this study will cause any disadvantage or discomfort. The potential physical and/or psychological harm or distress will be the same as any experienced in everyday life.

Where is the study run from?
University of Sheffield, the intervention was provided by Sheffield Sling Surgery (UK)

When is the study starting and how long is it expected to run?
June 2018 to November 2019

Who is funding this study?
University of Sheffield (UK), this study was conducted as part of a doctoral thesis in clinical psychology

Who is the main contact for this study?
Dr Abigail Millings (DClinPsy supervisor), a.millings@shu.ac.uk

Study website
https://osf.io/p23dw/

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Protocol/serial number
Nil known

Study information

Scientific Title
A randomised feasibility trial to evaluate the impact of the provision of an infant carrier and usage training to mothers of infants aged 0-6 weeks on maternal mental health and psychological wellbeing

Study hypothesis
The intervention will lead to lower postnatal depression scores, higher well-being scores, parenting self-efficacy and responsiveness, and breastfeeding frequency and duration, compared to the control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/02/2019, the University of Sheffield University Research Ethics Committee (UREC) (the University of Sheffield, Western Bank, Sheffield, S10 2TN; +44 (0)114 222 2000; psy-ethics@sheffield.ac.uk), ref: 024147

Study design
Single-centre randomized interventional study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Quality of life

Participant information sheet
Not available in web format

Condition
Maternal mental health in the postnatal period

Interventions
The intervention comprised the provision of free sling hire and training in how to use the sling from Sheffield Sling Library. Participation involves completing a questionnaire within 6 weeks of the birth of their baby, and subsequently being randomly allocated to receive the sling plus training intervention either as soon as was convenient after randomisation, or after a wait period of 3 months. Participants then either received the intervention or were added to the waiting list to receive the intervention after 3 months. Participants completed questionnaires 6 and 12 weeks after the first questionnaire. Randomisation was undertaken using a computer-generated random number sequence following a 1:1 randomisation ratio.

Upon completion of baseline measures, intervention participants are invited to attend a two-hour drop-in session at the sling library. These drop-in sessions are part of the sling library's usual provision at the time of the study. In this usual provision, parents are welcome to stay for as long as they wish within this time period. In usual provision, parents typically attend these sessions seeking advice and to try using a sling for the first time before buying or hiring, as well as seeking advice for slings that they are already using (e.g. through a previous purchase or hire). All contact between staff and parents takes place within one large room. As such, staff may sometimes demonstrate a sling to a group of interested parents, and parents are able to meet and chat with each other, offering opportunities for the development of social networks and social support.

To support the standardisation of session content and improve replicability, a checklist was created for use by sling library staff during interactions with study participants. Following the checklist, participants are offered sling training and advice, and a sling demonstration. Participants learn how to use one of two different types of sling: a 'Close Caboo' or buckle carrier, dependent on the needs and preferences of the mother and their infant. Participants are then given this sling, for free hire, for the duration of the study. Participants are invited to join an online sling community for further support and are given information about safe sling use and further sling library services. Throughout the study, participants are able to attend further

sling library sessions and swap their slings if they have any concerns or feel that another sling may be more suited to themselves and their infant. This flexibility was designed to replicate the responsive flexibility of usual provision by the sling library, but, unlike usual provision, at no cost to the participant.

Intervention Type
Behavioural

Primary outcome measure
Postnatal depression symptoms measured using the Edinburgh Postnatal Depression Scale at baseline, 6 weeks, and 12 weeks

Secondary outcome measures
Outcomes are assessed at baseline and 12 weeks:
1. Maternal psychological well-being scores measured using the Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS)
2. Parenting self-efficacy and responsiveness measured using the Parenting Sense of Competency Scale (PSCS)
3. Caregiving behaviour measured using the Caregiving Experiences Questionnaire (CEQ)
4. Breastfeeding frequency and duration measured using bespoke questionnaire items

Overall study start date
05/06/2018

Overall study end date
19/11/2019

Eligibility

Participant inclusion criteria
1. Expectant mothers due to give birth within the baseline data collection period
2. Able to travel to the sling library
3. Not regularly used a sling previously
4. Mothers of twins were included in the study but completed measures based on one child only

Participant type(s)
All

Age group
Adult

Sex
Female

Target number of participants
Following the recommendations of the National Institute of Health Research for feasibility studies, a sample size of 50-60 participants (25-30 per condition) was selected.

Total final enrolment
67

Participant exclusion criteria
1. Had used a sling previously or attended an antenatal workshop at a sling library
2. Infants had a serious illness or disability

Recruitment start date
01/04/2019

Recruitment end date
19/11/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Sheffield
Western Bank
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Sponsor information

Organisation
University of Sheffield

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Sponsor type
University/education

Website
http://www.sheffield.ac.uk/

ROR
https://ror.org/05krs5044

Funder(s)

Funder type
University/education

Funder Name
University of Sheffield

Alternative Name(s)
sheffielduni, University of Sheffield UK, theuniversityofsheffield, University of Sheffield in United Kingdom, University of Sheffield, UK, The University of Sheffield, Sheffield University

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/07/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository. Anonymous data will be posted on the Open Science Framework here: https://doi.org/10.17605/OSF.IO/P23DW indefinitely, on an open-access basis (anyone can access it). The dataset is the raw data (scale scores) for the quantitative variables. Participants consented to anonymous data being used by other researchers after the trial.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 3.0	22/02/2019	19/01/2023	No	No
Results article		10/11/2023	13/11/2023	Yes	No