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This Mum Moves: understanding the impact of an educational intervention supporting women to be active during and after pregnancy

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27/01/2020

Registration date
07/02/2020

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22/01/2021

Recruitment status
Suspended

Overall study status
Completed

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
This project aims to empower pregnant women and new mothers to make informed physical activity choices throughout pregnancy and beyond, through providing healthcare professionals with the tools to knowledgably and confidently discuss physical activity with them during the childbearing years. This will be supported by a wider campaign aimed at pregnant women and new mums, which will reinforce the messages provided by healthcare professionals as well as signposting women to further information and local services.

Who can participate?
Pregnant women with uncomplicated pregnancies living in a This Mum Moves delivery area who are over the age of 18, proficient in the English language, have conceived naturally and not had more than one previous miscarriage.
Healthcare professionals practising as a midwife or health visitors who are proficient in the English language, have been qualified for at least one year, and who have received This Mum Moves training.

What does the study involve?
Healthcare professionals opting to receive the intervention will attend training in physical activity guidance for pregnancy and the postpartum period. This training will focus on ensuring good awareness and understanding of the CMO guidelines for physical activity during pregnancy and after childbirth, and healthcare professionals will be provided with a 'Toolkit' of resources and information to help them in practice. Before attending training, healthcare professionals will complete a pre-training survey to understand their current awareness, confidence and knowledge in this area. Following training, midwives and health visitors will complete surveys immediately, 3 months and 6 months following the training to report on their knowledge, confidence and communication of physical activity information to pregnant women and new mothers.

Midwives or health visitors who have received the educational intervention and are participating in the project will identify pregnant women who meet the eligibility criteria during their initial

midwife appointment (at 10-12 weeks), 20 –week midwife appointment, or health visitor appointment (at 28 weeks).

Potential participants will be provided with very brief support/advice around physical activity, based upon current guidelines and supported by the toolkit, and will be asked if they would like to know more about the project and evaluation. If they agree to further information, they will be given a participant information sheet, and will be asked by their midwife or health visitor if they consent to be contacted by spear to complete the survey at up to 4 time points (or 2 time points for those recruited through health visitors; described above) during and after their pregnancy. If the potential participant agrees, a consent to contact form will be completed by the healthcare professional during the session. This form will be hosted on a secure digital platform. If the healthcare professional has no access to the internet, a paper copy is completed. This information will be copied onto the online form by the midwife, health visitor, or local collaborator/admin staff as soon as possible, with the paper copy subsequently securely disposed of. spear will contact pregnant women for whom consent to contact forms have been received, and invite them to consent to the study and complete the survey(s) online.

Following the first survey completion spear will initiate contact at the 3 subsequent time points (T2, T3, T4) for those recruited at the initial booking appointment; 2 subsequent time points for those recruited at the 20-week appointment (T3, T4) or 1 subsequent time point for those recruited through health visitors i.e. T4) for follow-up completion of the survey.

The intervention is designed to influence behaviour of healthcare professionals in practice, in relation to physical activity guidelines and their knowledge and application following specific training on this subject. The effect that the training has on the behaviour of the healthcare professionals and the pregnant women and new mothers will be tracked at the time points stated above for both healthcare professionals and pregnant women/new mothers.

Surveys will measure physical activity change in pregnant women and new mothers. As such, the intervention does not specifically prescribe physical activity and instead looks to identify whether training midwives and health visitors in physical activity guidelines has an impact on the physical activity behaviours of pregnant women and new mothers. Further information about activity levels during and after pregnancy, and details of the types of activities undertaken, specific barriers and enablers and patient empowerment will also contribute to answering the research questions.

Over the course of the study, data will also be collected in the form of site visits and focus groups/interviews. All participants (pregnant women and healthcare professionals) upon completion of each survey time point will be invited to ‘opt-in’ to be contacted by spear to participate in focus groups. The aim of these focus groups and interviews is to gain further, qualitative insight into the themes covered by the survey and the experiences of pregnant women, new mothers and healthcare professionals, in order to develop a comprehensive evaluation of the effectiveness of the programme.

What are the possible benefits and risks of participating?
The study is considered low risk and does not involve any invasive procedures. The intervention involves upskilling healthcare professionals (midwives and health visitors) to be able to effectively provide standard care advice including the benefits, risks, and burdens regarding physical activity to pregnant women and new mothers. Thus pregnant women and new mothers will only be encouraged to meet current guidelines regarding physical activity during pregnancy and postpartum. As it is intended pregnant women and new mothers meet these guidelines already it is not expected they will experience any risks or burdens greater than they would

normally.
Participants are able to withdraw from the study at any time. In the event that spear or the This Mum Moves project team is directly contacted by a woman about a still birth/miscarriage, the team will contact the midwifery/health visiting team to ensure that any message of condolence /response is appropriate, sensitive, and aligns with their site specific safeguarding policies.
Pregnant women who participate in the study and choose to be active during and/or after their pregnancy may benefit both physically and mentally as highlighted by the UK Chief Medical Officers guidance.
Healthcare professionals will benefit from the learning and development opportunity provided by the training and toolkit resources.
The details collected from participants may also help inform the way in which physical activity guidance is provided in the future.

Where is the study run from?
UKACTIVE (UK)

When is the study starting and how long is it expected to run for?
November 2019 to December 2021

Who is funding the study?
1. Sport England (UK)
2. National Institute for Health Research (NIHR) (UK)

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
250308

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 42785, IRAS 250308

Study information

Scientific Title
The impact of a toolkit for healthcare professionals to support physically active pregnancies upon physical activity levels in pregnant women and new mothers: This Mum Moves

Study objectives
The aim of the study is to examine the influence of the This Mum Moves project (a toolkit and associated campaign designed to support physically active pregnancies and postnatal periods) upon pregnant women's and new mother's physical activity levels.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/10/2019, (London - Brighton & Sussex Research Ethics Committee, Health Research Authority, Ground Floor, Skipton House, 80 London Road, London, SE1 6LH; +44 (0)207 104 8241; nrescommittee.secoast-brightonandsussex@nhs.net), ref: 19/LO/1244

Study design
Non-randomized cohort study

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Physical activity levels in pregnant women and new mothers

Interventions
Current interventions as of 30/10/2020:
This is a multi-phase design consisting of three phases. In phase one the toolkit will be developed and testing will commence in two pilot areas (Sheffield and Bexley). In phase two, testing will continue in Bexley and Sheffield, with three further sites identified to roll-out and test training informed by feedback from phase one. Phase three will look at a national roll-out and sustainable models.

Spear's mixed methods approach integrates social science disciplines that quantitatively assess and qualitatively explore all aspects of a programme. The evaluation includes assessment of behavioural and wellbeing outcomes, programme engagement, and barriers and enablers to activity in pregnant women and new mums. These outcomes will be assessed via an online survey that incorporates bespoke questions around activity, engagement, perceptions and attitudes alongside standard measures including a version of the International Physical Activity Questionnaire (IPAQ) which has been adapted for motherhood, ONS wellbeing scale (mental wellbeing), and Active Lives questions (self-efficacy and community trust). For those recruited by midwives at the initial booking appointment, surveys will be completed at up to 4 timepoints: T1. Trimester 1 (10-12 weeks); T2. Trimester 2 (20-22 weeks); T3. Trimester 3 (30-32 weeks); and T4. (6 months postnatal). Participants recruited at the 20-week appointment will complete up to 3 surveys (T2, T3, T4). Participants recruited by health visitors at the 28 week antenatal appointment will complete surveys at up to 2 timepoints: Trimester 3 (30-32 weeks); and T4. 6 months postnatal. Repeated measures analysis will be conducted providing target samples are achieved, otherwise cross sectional analysis will be undertaken. An online survey of healthcare professionals administered at the start and end of training, and three and six months later, will assess overarching and sustained impact on midwives' and health visitors' levels of confidence, skills and knowledge to deliver effective physical activity messages to pregnant women and new mums. It will also explore their perceptions and experiences of the toolkit, training and wider campaign.

Previous interventions:
This is a multi-phase design consisting of three phases. In phase one the toolkit will be developed and testing will commence in two pilot areas (Sheffield and Bexley). In phase two, testing will continue in Bexley and Sheffield, with three further sites identified to roll-out and test training informed by feedback from phase one. Phase three will look at a national roll-out and sustainable models.

Spear's mixed methods approach integrates social science disciplines that quantitatively assess and qualitatively explore all aspects of a programme. The evaluation includes assessment of

behavioural and wellbeing outcomes, programme engagement, and barriers and enablers to activity in pregnant women and new mums. These outcomes will be assessed via an online survey that incorporates bespoke questions around activity, engagement, perceptions and attitudes alongside standard measures including Short Active Lives questions (physical activity), ONS wellbeing scale (mental wellbeing), and Active Lives questions (self-efficacy and community trust). For those recruited by midwives at the initial booking appointment, surveys will be completed at 4 timepoints: T1. Trimester 1 (10-12 weeks); T2. Trimester 2 (20-22 weeks); T3. Trimester 3 (30-32 weeks); and T4. (6 months postnatal). Participants recruited by health visitors at the 28 week antenatal appointment will complete surveys at 2 timepoints: Trimester 3 (30-32 weeks); and T4. 6 months postnatal. Repeated measures analysis will be conducted providing target samples are achieved, otherwise cross sectional analysis will be undertaken. An online survey of healthcare professionals administered at the start and end of training, and three and six months later, will assess overarching and sustained impact on midwives' and health visitors' levels of confidence, skills and knowledge to deliver effective physical activity messages to pregnant women and new mums. It will also explore their perceptions and experiences of the toolkit, training and wider campaign.

Intervention Type
Other

Primary outcome(s)
1. Physical activity is being measured using a version of the IPAQ adapted for motherhood at 4 timepoints: T1 (10-12 weeks), T2 (20-22 weeks), T3 (30-32 weeks), and T4 (6 months postpartum)
2. Mental wellbeing is being measured using the ONS four personal wellbeing questions at 4 timepoints: T1 (10-12 weeks), T2 (20-22 weeks), T3 (30-32 weeks), and T4 (6 months postpartum)
3. Individual development is being measured using the Sport England Active Lives self-efficacy question at 4 timepoints: T1 (10-12 weeks), T2 (20-22 weeks), T3 (30-32 weeks), and T4 (6 months postpartum)
4. Social trust and community development will be measured using two Sport England Active Lives survey questions at 4 timepoints: T1 (10-12 weeks), T2 (20-22 weeks), T3 (30-32 weeks), and T4 (6 months postpartum)
5.Awareness of the UK national guidelines on physical activity during pregnancy is being measured by asking to what extent the participant agrees with statements taken from the guidance. This is measured at 3 timepoints: T1 (10-12 weeks), T2 (20-22 weeks), and T3 (30-32 weeks)
6. Awareness of the UK national guidelines on physical activity after childbirth is being measured by asking to what extent the participant agrees with statements taken from the guidance. This is measured at 1 timepoints: T4 (6 months postpartum)
7. Establishment of the point at which physical activity drops off is being measured through completion of bespoke physical activity questions and the IPAQ adapted for motherhood. This is being measured at 4 timepoints: T1 (10-12 weeks), T2 (20-22 weeks), T3 (30-32 weeks), and T4 (6 months postpartum)
8. Physical activities that are successful at re-engaging and activating participants will be measured through a bespoke question asking for examples of physical activities being undertaken at 4 timepoints: T1 (10-12 weeks), T2 (20-22 weeks), T3 (30-32 weeks), and T4 (6 months postpartum)
9. Maintaining or increasing physical preparation to give birth will be measured using a bespoke questions related to knowledge and awareness around physical preparedness to give birth at T4 (6 months postpartum)
10. Aiding physical recovery post-childbirth will be measured using bespoke questions regarding the impact of the programme on physical recovery post birth at T4 (6 months postpartum)

11. Survey data will be supplemented by qualitative evidence collated through interviews and/or focus groups during site visits to project locations

Key secondary outcome(s))
Healthcare professionals:
1. This Mum Moves training is being assessed through surveying healthcare professionals pre and post-training (T1 and T2)
2. Healthcare professionals are also being asked bespoke questions about their practice, knowledge and confidence in delivering messages around physical activity. This is pre and post-training (T1 and T2), and follow-up at 3 (T3) and 6 months (T4)

Completion date
30/12/2021

Eligibility

Key inclusion criteria
Pregnant women:
1. Pregnant
2. At least 18 years of age
3. Proficient in the English language
4. Conceived naturally

Professionals:
1. At least 18 years of age
2. Proficient in the English language
3. Practicing midwife or health visitor
4. Have been qualified for at least 1 year

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Key exclusion criteria
Pregnant women:
1. More than one previous miscarriage
2. Previous or existing condition(s) which might be caused or made worse by pregnancy (for example, asthma, diabetes, high blood pressure, etc)

Date of first enrolment
14/11/2019

Date of final enrolment
30/11/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Northern General Hospital
Sheffield Teaching Hospitals NHS Foundation Trust
Herries Road
Sheffield
South Yorkshire
Sheffield
United Kingdom
S5 7AU

Study participating centre
Sheffield Children's NHS Foundation Trust
Western Bank
Sheffield
United Kingdom
S10 2TH

Study participating centre
Darent Valley Hospital
Dartford And Gravesham NHS Trust
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Dartford
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DA2 8DA

Study participating centre
Bromley Healthcare OC Ltd.
Global House
10 Station Approach
Bromley

United Kingdom
BR2 7EH

Study participating centre
Harrogate & District NHS Foundation Trust
Lancaster Park Road
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HG2 7SX

Study participating centre
South Tyneside & Sunderland NHS Foundation Trust
Sunderland Royal Hospital
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SR4 7TP

Sponsor information

Organisation
UKACTIVE

Funder(s)

Funder type
Government

Funder Name
Sport England; Grant Codes: URN 2017010091

Funder Name
National Institute for Health Research (NIHR) (UK)

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No