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Parents and communities together (PACT)

Submission date
01/03/2017

Recruitment status
No longer recruiting

Registration date
20/03/2017

Overall study status
Completed

Last Edited
11/08/2020

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
From pregnancy onwards, the negative effects of social inequality and adversity effect children's long-term physical health, mental well-being, and emotional, cognitive, and behavioural development. Recent reports suggest that early interventions are the most effective way of addressing these lifelong issues. This is because social inequality and adversity begin to affect children before birth due to a combination of factors including nutrition, isolation, parental stress, access to services, and parenting environment. Research suggests that increasing social support for parents and in communities would be the most effective way to address the factors leading to poor outcomes in children. This is a new early intervention public health project for pregnant mothers and their infants which applies developmental health science through community organizing in order to improve the health outcomes for the next generation. In 2013, a small study was launched based on input from local mothers, health professionals, and academic research. This resulted in community-led support groups and educational workshops led by parents and professionals. The initiative was found to be acceptable to participants, feasible, and showed promising improvements in maternal stress and health knowledge. The primary aim of the current study is to produce robust evidence of the intervention's effect on the mental health, health literacy, and social capital of mothers, as well as the physical and cognitive development of their infants. The secondary aim is to develop a framework for this radical model of practice that communities and parents can expand upon, and discover if this new approach is worth exploring and using widely.

Who can participate?
Pregnant women between 22 - 34 weeks gestation attending midwifery clinics in Camberwell, Walworth and Bermondsey areas of Lambeth and Southwark

What does the study involve?
Participants recruited from the midwifery clinics covering the Camberwell and Walworth areas are invited to attend community support and education groups. The groups are free of charge and consist of "Parent University," an educational group run by parents and health visitors discussing pregnancy, birth, breastfeeding, weaning, emotional health, and other parenting issues, as well as "Mumspace," a play group designed to foster social support amongst mothers. Participants recruited from midwifery clinics covering the Bermondsey and Rotherhithe area do not receive the intervention but have access to any available resources for pregnant mothers in their area, excluding the resources mentioned above. All participants complete assessments

with a research midwife at their home at recruitment, 6 months after birth, and 12 months after birth. Each of these visits is expected to last from one to three hours, and data is collected about the mother's mental health, social capital, financial and health literacy, as well as physical and developmental outcomes with the infants after birth.

What are the possible benefits and risks of participating?
The benefits for participants include having easier access to health knowledge, relevant services, child play groups, community leadership, and social support through relationships formed with other mothers. If the study yields positive results, this project may be offered on a larger scale to mothers living throughout the UK. Your involvement may therefore benefit future mothers across the country. No risks are anticipated in taking part. The researchers liaise with midwifery teams about the pregnancy status of participants during and after recruitment to ensure no unexpected problems such as miscarriage have occurred. However, the participants are pregnant mothers and if they are assessed to have health risks, they are referred to specialist NHS services. Some questions in the questionnaires may be distressing, and participants are fully briefed beforehand. If they show signs of distress, the research midwife offers support, signposts the mother to appropriate services, pauses the assessment or has the mother withdrawn from the study.

Where is the study run from?
1. King's College Hospital NHS Foundation Trust (UK)
2. Guy's and St Thomas' NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
April 2015 to February 2018

Who is funding the study?
1. Guy's & St Thomas' Charity
2. King's College London

Who is the main contact?
Dr Derek Bolton

Contact information

Type(s)
Public

Contact name
Dr Derek Bolton

Contact details
Henry Wellcome Building
Institute of Psychiatry
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Additional identifiers

Protocol serial number
182843

Study information

Scientific Title
Parents And Communities Together (PACT): strengthening local babies' futures by community-led action

Acronym
PACT

Study objectives
The main hypothesis is that mothers allocated to the community intervention group will show improved maternal social capital, mental health, and health literacy, as well as comparatively better infant health and developmental outcomes in the first 12 months than the infants in the control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NHS National Research Ethics Service Committee London–Fulham, 12/02/2016, ref: 15/LO/1227

Primary study design
Observational

Study design
Matched case-control study

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Mental health, health literacy and social capital

Interventions
Participants recruited from the Camberwell and Walworth will be allocated to receive the intervention which is comprised of two components:
1. The social support network will comprise three main hubs, one established during the Pilot at Camberwell Salvation Army, at St Michaels and All Angels church in Camberwell, and the third in Walworth, based at a Primary School. The hubs will host parent-led weekly meetings with provided childcare assistance during attendance. This is to provide an accessible and non-judgmental space for themed discussions about children, parenting, and personal concerns, facilitating mutual social support among the mothers.
2. The second component involves 12 health education workshops co-ordinated by a health visitor but are parent-led with input from experts (e.g. midwives) and professionals as required. The first two sessions are ante-natal and the following sessions are ante and post-natal. The

workshops will cover mental health and parents, how hormones impact on feelings, health behaviours that benefit baby's healthy development, nutrition, infant learning, and parenting skills. This format and syllabus was co-developed with health care professionals and parents in the pilot study, the latter requesting a need for health education and a place to share concerns. Participating mothers will also be supported by a Citizens UK organiser to work together with other parents to advocate on health literacy topics, to express views to health services and commissioners, and tackle community issues they have identified that inhibit the wellbeing of parents and babies in Camberwell and Walworth - issues pertaining to the wider social determinants of health. As was found in the pilot, it is expected that the community-led groups will involve and grow according their participants. However, the two evidence-based features of the intervention (social support and health education) will remain as the core components of the intervention.

Women recruited in the Bermondsey and Rotherhithe area will be allocated to the control group and will receive no intervention. They will have access to any available resources for pregnant mothers in their area, excluding the resources mentioned above.

All participants complete assessments with a research midwife at their home: at recruitment, 6 months after birth, and 12 months after birth. Each of these visits is expected to last from one to three hours, and where data is collected about the mother's mental health, social capital, financial and health literacy, as well as physical and developmental outcomes with the infants after birth.

Intervention Type
Behavioural

Primary outcome(s)
1. Maternal mental health:
1.1. Symptoms of anxiety, measured using the Generalised Anxiety Disorder Assessment (GAD7) at baseline, 6 months after birth, 12 months after birth
1.2. Symptoms of depression, measured using the Patient Health Questionnaire (PHQ9) at baseline, 6 months after birth, 12 months after birth
1.3. Frequency of positive thinking, measured using the Automatic Thoughts Questionnaire Revised (ATQR) at baseline
2. Health literacy, measured at baseline and 6 months after birth:
2.1. Self-reported difficulties in accessing, understanding, appraising and applying information in tasks concerning decisions making in healthcare, disease prevention, and health promotion, measured using the European Health Literacy Survey Questionnaire (HLSEQQ47)
2.2. Health literacy, literacy and numeracy skills, measured using the Newest Vital Sign (NVSUK)
3. Social capital, measured using the Social Capital Integrated Questionnaire – short version (SCIQ) at baseline, 6 months after birth, 12 months after birth
4. Infant development, measured at 12 months after birth using:
4.1. The Infant-Toddler Social and Emotional Assessment (ITSEA)
4.2. Infant birth weight and weight trajectory, measured from routine data sets collected at birth and by health visitors

Key secondary outcome(s)
1. Parenting, measured at baseline, 6 months after birth:
1.1. Stress in the parent-child system, measured using the Parenting Stress Index – 4th Edition (PSI-4) Short Format at 6 months after birth
1.2. Maternal attachment and bonding, measured using the Maternal Antenatal Attachment

Scale (MAAS) at baseline
1.3. Post-birth maternal attachment and bonding, measured using the Maternal Postnatal Attachment Scale (MPAS) at 6 months after birth
2. Financial literacy, measured using the Financial Literacy Survey Questionnaire at baseline
3. Maternal general health behaviour, such as smoking and alcohol consumption during pregnancy, diet and initiation and duration of breastfeeding, routinely assessed by maternity services
4. Routine outcome measures, such as gestation length, mode of birth, breastfeeding data and condition at birth, measured using routine datasets collected in maternity care
5. User satisfaction, measured using the Social Support Programme Acceptability Rating Scale at 6 months and 12 months after birth
6. Total cost and the cost per participant, calculated looking at service use in the 6 and 12 months after birth
7. Service use, measured using the Strengthening Babies Future Adult Service Use Schedule (SBF ADSUS) at 6 months after birth

Completion date
28/02/2018

Eligibility

Key inclusion criteria
1. Pregnant women between 21-26 weeks gestation
2. Attending midwifery clinics in Camberwell, Walworth and Bermondsey areas of Lambeth and Southwark
3. The infants cared for by these women
4. Aged 19 or over

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Total final enrolment
136

Key exclusion criteria
1. Suitable for referral to specialist services according to current guidance, e.g. below 19 years old, referred to local Family Nurse Partnership, history of or current depression to specialist mental health
2. Living in postcodes that will be invited to take part in Lambeth Early Action Partnership (LEAP is a Big Lottery funded initiative nearby)

Date of first enrolment
27/04/2015

Date of final enrolment
31/03/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Guy’s Hospital
Great Maze Pond
London
United Kingdom
SE1 7EH

Study participating centre
King's College London
Strand
London
United Kingdom
SE5 8AF

Study participating centre
King's College London (KCL)
Community Midwifery Centre
45-47 Caldecot Road
London
United Kingdom
SE5 9RS

Sponsor information

Organisation
King's College London

ROR

https://ror.org/0220mzb33

Funder(s)

Funder type
Charity

Funder Name
Guy's and St Thomas' Charity

Alternative Name(s)
Guy's and St Thomas' Charity, Guy's and St Thomas' Foundation, GSTTFoundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Funder Name
King’s College London

Alternative Name(s)
King's, Collegium Regium apud Londinenses, Collegium Regale Londinense, Collegium Regale Londiniense, KCL

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made 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?
Results article	results	18/04/2020	11/08/2020	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	evaluation	07/04/2020	11/08/2020	Yes	No
Participant information sheet	version V3	22/09/2015	20/03/2017	No	Yes
Participant information sheet	version V2	07/08/2015	20/03/2017	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes