Can a community-led intervention offering social support and health education improve maternal health?

Submission date	Recruitment status	Prospectively registered
27/06/2019	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
11/07/2019	Completed	Results
Last Edited	Condition category	Individual participant data
10/06/2020	Pregnancy and Childbirth	Record updated in last year

Plain English summary of protocol

Background and study aims

Maternal health may be improved through stronger support networks and better health literacy. At a population level, there needs to be a collaboration between statutory services (e.g. midwifery and health visiting services), civic organisations (e.g. churches, schools) as well as community groups and parents themselves. Key elements in improving community engagement are working together to develop an intervention with the community groups taking the lead. This study evaluates such an intervention developed for ante-natal and post-natal mothers, offering social support and health education. The intervention was based in a deprived south London borough. It aims to assess changes among mothers attending the intervention on depression, anxiety, health literacy, social capital and a satisfaction measure after 6 months' attendance.

Who can participate?

All mothers who attend the intervention are invited to participate.

What does the study involve?

The study involves answering questions on the questionnaires specified.

What are the possible benefits and risks of participating?

The benefits are to do with helping the team discover if the intervention is successful in achieving its aims of improving mental health symptoms, as well as health literacy and social capital and whether the programme was acceptable. The risks were to do with the inconvenience of sitting and answering questions. Risks associated with confidentiality would be taken care of by ensuring strict confidentiality protocols are followed.

Where is the study run from?

The study is run from the Institute of Psychiatry, Psychology and Neuroscience, King's College London which is based in Denmark Hill.

When is the study starting and how long is it expected to run for?
The overall study started on 1 January 2016, started recruiting on 1 May 2016 and finished on 30 June 2017.

Who is funding the study? Guys and St Thomas Charity are funding the study.

Who is the main contact?

Dr June Brown, Senior Lecturer in Clinical Psychology is the main contact.

Study website

https://www.kcl.ac.uk/ioppn/depts/psychology/research/researchgroupings/pact

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

PACT1

Study information

Scientific Title

Can a community-led intervention offering social support and health education improve maternal health? A repeated measures evaluation of the PACT project run in a socially deprived London borough at 6 months follow-up

Acronym

PACT

Study objectives

- 1. Will the PACT intervention lead to improvements in maternal mental health, social capital and health literacy?
- 2. What are the characteristics of the mothers attending the intervention?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 25/02/2016, the King's College London Research Ethics Committee (Research Ethics Office, Franklin Wilkins Building, 5.9 Waterloo Bridge Wing, Waterloo Road, London SE1 9NH; pnm@kcl.ac.uk; 020-7848-4020/4070/4077), ref: HR15/162334.

Study design

Single centre, interventional, non-randomised repeated measures study.

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Community

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied

Women who are pregnant or have recently given birth.

Interventions

The aim of PACT was to use the tools of community organising to build the capacity of local parents and communities to work with local statutory partners to improve children's early developmental outcomes and parental mental health outcomes.

The PACT intervention aimed to improve social support (through Mumspace) and health education (formally through Parent University as well as informally in Mumspace).

- 1. The social support groups (Mumspace) were held weekly and ran for 2 hours. There were ongoing weekly groups at each of the three local hubs. Parents spent part of the session playing with their children and talking to other parents over a cup of tea and then part of the time in a separate space when volunteers helped with their children. They also participated in parent led workshops, on such topics as parenting, immunisations, importance of play and going back to work, motherhood, caring for children, parenting, and personal concerns. Topics for workshops were decided by participants in quarterly meetings. The greater joint decision-making created a welcoming and non-judgmental feel that reduced barriers that some communities report when accessing local statutory provision. There was also a Spanish-speaking group but this was not evaluated.
- 2. "Parent university" was a 12-week health education course co-designed with parents, health visitors and midwives which was co-led by parents and professionals. Parents with older children co-facilitated the group, with an emphasis on peer sharing rather than didactic teaching. Each session comprised a talk on a topic followed by discussion. Topics covered birth and childcare, mental health aspects in parenting, how hormones impact on feelings, health behaviours that benefit baby's healthy development, nutrition, infant learning, parenting skills and minor ailments. The parent university was co-ordinated by a health visitor and sessions lasted for two hours. Mothers "graduated" at the end of the course if they had completed 8 out of the 12 sessions.

Participants are invited to take part in both groups, and mothers could "graduate" from Parent University into Mumspace and vice versa.

In addition, at one of the sites, there was a "Baby Bank," where child clothing, equipment, and accessories were donated and given to mothers in need. Mothers were also given the opportunity to attend free or highly subsidized educational opportunities provided by PACT such as first-aid courses, parenting courses, healthy eating workshops, pregnancy yoga, meetups, etc.

Intervention Type

Mixed

Primary outcome measure

Anxiety symptoms are measured using the Generalized Anxiety Disorder Questionnaire (GAD-7) at baseline and 6 months follow-up.

Secondary outcome measures

- 1. Depression symptoms are measured using the Patient Health Questionnaire (PHQ-9) at baseline and 6 months follow-up.
- 2. Health Literacy is measured using the Newest Vital Sign UK (NVS-UK) at baseline and 6 months follow-up.
- 3. Social Capital is measured using the Arizona Social Support Interview Schedule (ASSIS) at baseline and 6 months follow-up.
- 4. Acceptability is measured using the Social Support Programme Acceptability Rating Scale (SSPA-RS) at baseline and 6 months follow-up.

Overall study start date

01/01/2016

Completion date

31/12/2017

Eligibility

Key inclusion criteria

- 1. Aged over 18.
- 2. Female.
- 3. The parent of at least 1 child.
- 4. Speak sufficient English to complete the questionnaires.
- 5. Have attended the intervention for less than 2 months at baseline.

Participant type(s)

All

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

61

Key exclusion criteria

N/A

Date of first enrolment

01/05/2016

Date of final enrolment

30/06/2017

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Salvation Army (Camberwell Corps)

105 Lomond Grove Camberwell London United Kingdom SE5 7HG

Sponsor information

Organisation

King's College London

Sponsor details

Institute of Psychiatry, Psychology and Neuroscience De Crespigny Park London England United Kingdom SE5 8AF 020-7848-0002 ioppn-pr@kcl.ac.uk

Sponsor type

University/education

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

Results and Publications

Publication and dissemination plan

We are planning to publish this study, a case-control study as well as a qualitative study.

Intention to publish date

31/12/2020

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr June Brown (June.Brown@kcl.ac.uk). Anonymised data is available until Dec 2023 as this data is being kept for 7 years.

IPD sharing plan summary

Available on request