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Randomised controlled trial (RCT) and economic evaluation of the Family Links Nurturing Programme

Submission date 23/07/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/09/2008	**Overall study status** Completed	
Last Edited 28/08/2018	**Condition category** Other	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
LOC2549T

Study information

Scientific Title

Promoting health and wellbeing with the Family Links Nurturing Programme (FLNP) in South Wales: a randomised controlled trial and economic evaluation

Study objectives
Sub-optimal parenting is a common risk factor for deleterious social educational and health outcomes, increasing the risk of educational failure, delinquency, crime and violence, child and adolescent mental health problems, common mental disorders in adulthood, drug and alcohol misuse and teenage pregnancy. There is also evidence to suggest an effect on physical health throughout the life course. Most parenting programmes have been developed in the USA in the context of delinquency prevention for targeted or indicated groups (high risk families or those where problems have already occurred) and the main theoretical underpinning for these programmes is behaviour management. The Family Links Nurturing Programme (FLNP; http://www.familylinks.org.uk/nurturing/index.htm) focuses on family relationships as well as behaviour management and may be better placed to improve educational and health outcomes in the context of universal provisional than the primarily behaviour management programmes. Developed in the UK voluntary sector, FLNP is popular with practitioners in South Wales, has impressed policy makers throughout the UK, evaluates well in before/after and qualitative studies, but lacks an RCT evidence base.

Ethics approval required
Old ethics approval format

Ethics approval(s)
This study was approved by the NHS South East Wales Local Research Ethics Committee on the 7th October 2008 (ref: 09/WNo01/50).

Primary study design
Interventional

Study design
Multi-centre, investigator-blind, randomised controlled trial

Study type(s)
Other

Health condition(s) or problem(s) studied
Parenting

Interventions
The participants will be allocated to the intervention and control groups in equal numbers (144 participants in each group).

The FLNP is a ten-week programme involving 2-hour sessions each week for groups of 6-10 parents. The programme is structured and aims to provide experiential knowledge and insight through the use of guided discussion, role play and home work. Parents set targets for themselves each week and report back on progress the following week. The four building blocks of the programme are:
1. Development of self-awareness and self-esteem
2. Appropriate expectations
3. Positive discipline
4. Empathy

The programme is eclectic, drawing on social learning theory and psychotherapeutic insights. It is founded on the belief that empathetic insight into emotional determinants of behaviour is important for both positive relationships and behaviour management. It aims to provide parents with insights into the origins of self-esteem and positive relationships by drawing on their own experiences as children. The programme thus supports parents in improving their own relationships with others as well as with their children. Parents are given a copy of the programme book 'The Parenting Puzzle', and each programme is run by two facilitators who receive face-to-face supervision three times during the course of the programme from an experienced programme facilitator. The capacity to make compassionate relationships with the parents in the groups, to empower and to support them, and at the same time provide a tightly run, structured group programme is seen as essential to success.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
A composite index derived from the following:
1. A parent report measure of parent-child relations
2. Home Observation for Measurement of the Environment (HOME) inventory, recorded during the data collection home visit

The primary outcome measure will be collected immediately before the intervention and 6 months after completing the parenting programme.

Key secondary outcome(s)
1. To investigate and establish the cost consequences of the FLNP using established economic modelling techniques. The cost consequences will be measured using a cost consequences analysis, which allows an array of outcome measures to be considered alongside the cost of the programme. This will compare FLNP with no intervention in parents and children from public purse, societal and parents' perspectives. Modelling will examine the sensitivity of the results to a range of assumptions. Data will be collected before, during and 6 months after the programme.

2. To investigate the fidelity of programme implementation and delivery by practitioners in Cardiff, Newport and Torfaen. Programme fidelity will be assessed using video recordings of three randomly selected sessions in each programme (with parental consent) coded by Family Links staff. In addition, supervision sessions with the facilitators will be audio recorded and coded by Family Links staff that will also have access to flip chart recordings of changes and insights made by parents during group sessions. Uptake rates, attendance rates (number of sessions attended), drop out rates, mother/father ratio of attendees, attendance and dropout by day and time of group will also be reported.

3. To investigate the views and perceptions of families receiving the FLNP in Cardiff, Newport and Torfaen, including perceived value attributed to the programme. The views and perceptions of families will be gained by interviewing 12 intervention group parents representing different cultural and social backgrounds and different experiences (positive and negative) after the programme to gather information on most and least valued aspects of programme, rating of the facilitators, and ways of improving the programme. We will also ask to interview 12 parents who decline to take part in the study to determine possible ways of improving recruitment.

4. To act at all times in the best interests of children and their families and with due regard to all ethical and legal responsibilities, including Criminal Records Bureau checks for all staff working with children and compliance with the Data Protection Act

Completion date
31/03/2011

Eligibility

Key inclusion criteria
Parents of children aged 2 - 4 years old in children centre areas in Cardiff, Newport and Torfaen in South Wales

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Parental age less than 16 years at study entry

Date of first enrolment
15/09/2008

Date of final enrolment
31/03/2011

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Health Sciences Research Institute
Coventry
United Kingdom
CV4 7AL

Sponsor information

Organisation
University of Warwick (UK)

ROR
https://ror.org/01a77tt86

Funder(s)

Funder type
Government

Funder Name
Cardiff County Council (UK) (ref: LOC2549T)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2013		Yes	No
Protocol article	protocol	23/06/2010		Yes	No