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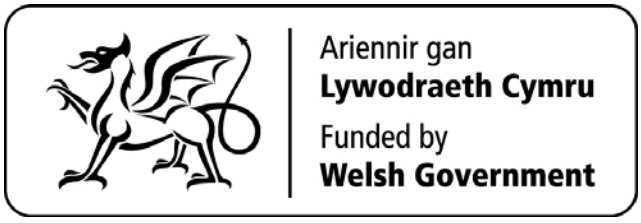
Promoting health and wellbeing with the Family Links Nurturing Programme (FLNP) in South Wales: A Randomised Controlled Trial and economic evaluation



Prepared by:
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Final Study Report

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Abstract

Background

This trial investigated whether the Family Links Nurturing Programme (FLNP), a ten week programme of weekly two hour sessions available to all families in deprived areas, had an impact on parenting and child and parental wellbeing and at what cost.

Methodology

A randomised controlled trial of the FLNP. Families were recruited from Flying Start Programmes in deprived areas of south Wales. Outcome measures were collected at baseline, at three months and at nine months. The primary outcomes were composite measures (from the HOME inventory and the MORS Index) of negative and supportive parenting. There were two objective measures of parenting; a video of parent child interaction at a child's mealtime and a five minute speech sample of parents' describing their child and their relationship with the child. Child wellbeing was assessed with PedQL: parent report, and the PrePACS. The Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) and Parenting Stress Index (PSI) were used to measure parental wellbeing. A mixed effects model analysis compared change in outcomes in groups as allocated. This report covers the findings at three and nine months. A cost consequences and cost utility analysis based on the SF-6D was undertaken including implementation, parental, NHS and social care costs against primary and secondary outcomes. Qualitative

interviews were undertaken with purposively sampled parents who participated in the trial and the programme; did not participate in the trial; and did not participate in the trial or the programme and a thematic analysis was undertaken, focusing on motivation for participating or refusing the trial and perceived value of the programme.

Findings

143 families were randomly allocated and recruited to each of the intervention and waiting list control groups. Follow up was 84% at nine months. There were no significant differences in change scores on the primary or secondary outcomes between control and intervention groups at three or nine months. Estimated differences at nine months were as follows (differences with a positive sign indicate more benefit in intervention group):

Primary outcomes: *negative parenting* 0.90; p=0.52, 95% CI -1.90to3.69 and *supportive parenting* 0.17; p=0.67, 95% CI -0.61 to 0.94).

Secondary outcomes:1) Parenting: Speech Sample -warmth of initial rating 0.01; p = 0.97; 95% CI -0.39 to 0.40; -% of negative comments -0.01, p=0.75; 95% Cl – 0.10 to 0.07; 2) Child Wellbeing: PrePACS- *hyperactivity (weekly*) 0.86; p=0.35; 95% CI -0.95 to 2.66; *hyperactivity (typical)* -0.03, p=0.98; 95% CL -2.18 to 2.12;*conduct (weekly)* 0.03*;* p=0.98; 95% CI -2.57 to 2.64; *conduct(typical)* -0.12, p = 0.92; 95% CL -2.47 to 2.24; *internalising (freq)* 0.13,p = 0.78; 95% CI –0.82 to 1.09; *internalising (reassure*) -0.29, p=0.62; 95% CL -1.43 to 0.85; mealtime video*:- % negative interactions* 0.0458, p=0.131;95% Cl-0.0137, 0.1053; *rate of negative interactions (length)* 0.1091,p=0.455;95% Cl -0.1786, 0.3968; *rate of positive interactions (length)* 0.7539,p=0.248;95% Cl -0.5298, 2.0376;

r*ate of negative interaction (involvement)* 0.0306; p=0.910;95% Cl -0.5044, 0.5655; *rate of positive interactions (involvement)* 1.6221,p=0.259;95% Cl -1.2051, 4.4494. *PedsQL* 1.50, p=0.19; 95% CI -0.74 to 3.74; 3)Parental Wellbeing -*WEMWBS* 0.49; p=0.67 95% CI -1.82 to 2.80; *Parenting Stress Index:* –0.80; p=0.75 95% CI -5.74to 4.14. Attendance at the programme by intervention group families was low: one third did not attend at all (n = 49) and less than half completed the course (n = 68). 10% of families in the control group attended the programme before the 9 month follow up and 9% accessed other parenting interventions in that period compared to one in the intervention group. Analysis by number of sessions attended (treatment received) showed similar findings with regard to primary outcomes (*negative parenting* β= 0.21, p=0.22; 95% CI -0.13 to 0.55) *supportive parenting*; β = 0.06, p=0.22; 95% CI -0.04 to 0.15). The PrePACS Hyperactivity scale (weekly) showed significantly more improvement for the FLNP group amongst parents attending five or more sessions (2.33, p=0.022; 95%CL 0.34-4.32). Differences in all other secondary outcomes were non-significant with 13 out of 16 showing more improvement in the FLNP group than control. Exceptions were PrePACS scale items Internalising (Freq) and Internalising (Reassure) and the mealtime video % positive interactions(involvement).

Costs of implementing the intervention were relatively low: £648.38 (SD=97.84 per family attending). There was no significant difference in parent QALYs in intervention and control groups. When a mean imputation or complete case analysis was undertaken, the incremental cost per QALY gained was £21,600 at 5 years and £12,960 at 10 years. Qualitative analyses showed motivation levels for doing both the course and the research to be mixed. Those who did the course were generally positive about the

experience and reported changes in their parenting or understanding of their child and family relationships consistent with the course materials. Factors reported to inhibit change included lack of partner support. Factors reported to have inhibited participation in the research included the requirement to be videoed, and wanting immediate help with parenting. Factors which encouraged participation in the trial included wanting to help others.

Conclusions

This trial encountered issues that are known to be related to implementation of RCTs of health/wellbeing promotion programmes in community settings, including low exposure to intervention and contamination of control group. Against a backdrop of improvement in all outcomes for the FSP families in this trial, primary and secondary outcomes showed no significant differences at 3 or 9 months between FLNP and control group. The direction of many non-significant changes, especially in the 'as treated' analyses suggest the possibility of positive effect. Qualitative findings show parents who were interviewed to have benefited from the programme and indicate the possibility that the most motivated parents may have avoided participation in order to access parenting help quickly outside of the trial. On the basis of parent wellbeing and over a 10 year period, the programme falls within national guidance for cost effectiveness. These findings are compatible with cost effectiveness of the FLNP offered on a universal basis to improve wellbeing and parenting in deprived areas.

Registration

The trial is registered with Current Controlled Trials ISRCTN13919732,

http://www.controlled-trials.com/ISRCTN13919732/13919732

and on the UK Clinical Research Network Study Portfolio, UKCRN ID 5814,

http://public.ukcrn.org.uk/search/StudyDetail.aspx?StudyID=5814.

Chapter 1: Introduction

Parenting is an important determinant of health and wellbeing. It plays a role in determining future mental health [1,2,3,4], health related lifestyles (including healthy eating [5], substance misuse [6] and teenage pregnancy [7]), injury rates [8], aspects of physical health [3,9-12], social competence [13,14] and educational achievement [15,16]. Suboptimal parenting is therefore a risk factor for a number of health, social and educational outcomes and improvements in parenting could contribute to achieving a wide range of current policy goals.

Group parenting programmes can change parenting practices and the evidence that programmes are cost effective in treating conduct disorder and child behaviour problems is strong [17,18].There is good evidence that they are also effective in preventing behavioural problems in high-risk groups identified by socio-economic deprivation, ethnic group and experience of life events [19-22]. Most of this evidence relates to two programmes: the Incredible Years (IY) Programme [23, 24] and Triple P (TP) [25, 26].

Current government policies relating to parenting in the UK recognise the need for universal parenting support to complement targeted and indicated approaches [27, 28, 29, 30]. This ranges from provision of information and support to universal access to parenting programmes [31]. Such recommendations derive from observations relating to the prevalence of sub-optimal parenting [32], the inefficiency of targeting on the

basis of identifiable risk factors [33,34] and the potential for realising change in high risk as well as whole population groups by reducing the stigma which may be attached to parenting support [33-35]. Given the range and prevalence of health and social outcomes on which parent-child relationships have an influence [2,3,5-16], universal approaches are appealing.

The Family Links Parenting Programme [36] (FLNP), has much in common with IY and TP but focuses more on the quality of the parent-child relationship and the parents' well-being. It conforms to criteria for effective programmes [37]; meets most or some of the criteria on all four elements of the National Academy for Parenting Research Programme Evaluation Toolkit [38] and is listed on the database of parenting programmes by the Children's Workforce Development Council Parenting Practitioners [39]. The current evidence base for FLNP includes qualitative research showing that parents, recruited through schools, value the programme and perceive it to have an impact on family relationships, children's behaviour and their own mental health [40]; before and after studies in community groups showing impact on self report measures of relationship quality and well-being [41]; and routine evaluation by parents attending programmes showing that the great majority value the programme [42].

None of this evidence allows estimation of the extent of programme impact relative to changes occurring in a control group or enables economic modelling of the costs and effects necessary to assess the relative value of expenditure on such programmes.

UK government departments are increasingly making use of a hierarchy of evidence derived from medical research in which evidence from randomised controlled trials (RCTs) and systematic reviews of such trials is considered more robust than that from other types of study. As a result, funding for programmes with no RCT evidence base, like FLNP, is being withdrawn and re-invested in programmes for which there is an RCT evidence base.

FLNP was being provided on a universal access basis in the context of Flying Start Programmes (FSP) in south Wales. Flying Start Programmes serve deprived areas in a similar model to Sure Start in England. The FLNP was popular with practitioners and parents. Concern that funding for the programme might be withdrawn led, initially three and latterly four, county councils to commission an RCT of the programme in south Wales with financial support from the Welsh Assembly Government.

Chapter 2: Methods

Participants

All parents with children aged 2-4 years old living in the catchment area of a FSP who had not previously attended a FLNP were eligible for recruitment. Parents were approached by FSP practitioners and offered a participant information leaflet. If they expressed interest they were put in contact with the research team for more information. All participants gave written informed consent. Participant families were initially recruited from Cardiff, Newport and Torfaen and subsequently also from Caerphilly. Baseline data were collected in families' homes before randomisation, after the FLNP course (three months after baseline) and six months after the completion of the course (nine months after baseline).

Data on the resources associated with implementation of FLNP were collected from structured interviews with key staff at each of the four study sites, collection of financial information at each site (e.g. estimates of room hire and crèche facilities) and discussions with the main trial team. Implementation costs associated with the programme were estimated by multiplying resource usage by unit costs (where available) sourced from published 2009 PSSRU reference costs for health and social care [43] or from costs provided during interviews. The main cost categories established included staff (facilitator) and administration costs, training, venue hire, crèche provision and course materials/refreshments. Due to variability within and between each study site on staffing arrangements (e.g. grade and mix of staff used to deliver

FLNP programmes), costs were separately estimated for each site and the mean cost per programme and per family attending derived from these estimates.

We gathered data for the consort diagram on reasons why families refused to take part in the trial and explored these in more depth using qualitative interviews. Qualitative data were also collected on parents who took part in the trial and parents who took part in the FLNP. These interviews gathered data on reasons for agreeing to the research, reasons for wanting to do the FLNP, perceived impact of the programme on themselves and their families and the most valued and least valued aspects of the course. Sampling was based on parental consent and availability but within these confines aimed to cover families from a spectrum of social and family circumstances with equal numbers from all four county council areas.

Ethics

Ethical approval for the overall study was granted by the North West Wales Research Ethics Committee (08/Wno01/50) on 6th October 2008. Minor adaptations to the outcome measures, indicated following piloting, were subsequently approved (AM01) on 22nd December 2008.

Trial Steering Group

A trial steering group was established with an independent chairman and members with expertise in statistics, early years intervention studies, child psychiatry and with parental representation.

Intervention

FLNP is a ten week course comprising weekly two hour sessions for groups of 6-10 parents. It is structured and aims to provide experiential learning and insight through the use of guided discussion, role play and home work. The programme aims to develop self awareness and self esteem, appropriate expectations, positive discipline and empathy. Parents are given a copy of the programme book, the 'Parenting Puzzle' and each programme is run by two facilitators. A crèche is provided for the duration of the course. The programme is delivered in term times and entry to the group is closed after the third session. There are therefore only three opportunities for recruitment each year. Group size is limited but needs to be above a threshold. In order to deliver viable groups parents who were not taking part in the trial attended groups with parents who were. Families randomised to the control arm of the trial were offered the programme after the 9 month follow up data collection period was complete.

Objectives

This trial aimed to test the hypothesis that the Family Links Nurturing Programme improves parenting and child and parent wellbeing. The trial objectives were to:-

1. Measure the effectiveness of the Family Links Nurturing Programme (FLNP), in securing beneficial impact on parenting and health and social outcomes for young children and their families in the short and medium term.
2. Measure the cost consequences and cost utility of the FLNP.
3. Investigate the fidelity of programme implementation and delivery by practitioners in the trial sites and estimate effects on outcomes.
4. Investigate the views of families receiving the FLNP in the trial sites related to perceived value attributed to the programme and reasons for participating or not participating in the trial.

Outcomes

The primary outcome was a composite index modelled on that developed for the evaluation of Sure Start [44] which provides two scales representing negative parenting and supportive parenting. In Sure Start these scales proved approximately normally distributed and sensitive to small differences between groups. Our measure was derived from observations made and questions administered during a home visit and recorded according to the HOME inventory [45], and responses to a parent report measure of parent child relations (adapted Mothers' Object Relations Scales (MORS), unpublished data) collected at the same visit. Factor analysis showed very similar findings to those

derived in Sure Start. Given the much larger sample in the Sure Start study, variables in this study were weighted with Sure Start weightings to derive the composite variables. To supplement this primary outcome, objective data were gathered using a video of a child's mealtime coded according to the Mellow Parenting Scheme [46] and a five minute speech sample capturing the parents' description of their children in the 2-4 age range and their relationship with each child [47].

A range of secondary outcome measures were used to capture health and wellbeing in parents and children. For child wellbeing these were the PedsQL: parent report [48]; and the pre-school version of the Parent Account of Child Symptoms (PrePACS) [49]. The former is a generic health related quality of life measure validated for use as a measure of utility in health economic analyses and the latter is a clinically validated measure of childhood emotional and behavioural problems. Parental wellbeing was assessed using the Warwick-Edinburgh Mental Well-being Scale (WEMWBS) [50], a 14 item self-report measure of positive mental health and wellbeing, Parenting Stress Index [51] and a SF-6D [52], a self-report health related quality of life measure validated for health economic analyses.

The objective measures of parenting (the video and speech sample) and the PrePACS measure of child wellbeing were collected during a home visit to the families at baseline before the programme starts and again at nine months. Self-completion questionnaires covering the parent/self-report outcomes were collected at baseline, three months and nine months.

Sample size

We aimed to recruit 144 families into each of the control and intervention groups (288 in total). This sample size was sufficient to detect a standardised effect size of 0.4 at 85% power and alpha of 0.05 in the primary outcome measure if there is no clustering. Since the intervention was offered to groups, clustering may be present. With a total sample size of 288 the trial is powered to detect a standardised effect size of 0.6 for an intra-class correlation coefficient of 0.178 or less. Design effects are typically small in parenting programme trials. One recent study of the IY's programme in which both randomisation and intervention were subject to design effects identified intra-class correlations attributable to 'group' effects ranging from 0 to 0.16 [22]. In our study, design effects could be attributable to the group-based nature of the intervention only, as randomisation was at the level of individual families. No interim analyses were planned or conducted.

Randomisation

- ***Sequence generation***

Randomisation was stratified by Local Authority (Cardiff, Newport and Torfaen initially then Caerphilly in addition). Minimization randomisation [53] was used, increasing the chance of allocation to the smaller group to 0.667 when there was an imbalance to allow balance to be maintained between groups whilst also maintaining random allocation.

- ***Allocation concealment***

The minimisation randomisation prevented a situation where allocation outcome could be predicted by researchers or practitioners by allowing a small difference between groups to influence randomisation but ensuring that it was always possible to be allocated to either intervention or control group. The allocation sequence was concealed until after interventions were assigned.

- ***Implementation***

The randomisation service at Warwick Clinical Trials Unit generated the random allocation sequence. Families were enrolled by the researchers in Cardiff, Newport, Torfaen and Caerphilly (MA, BA, SW, LW, AN) who notified the CTU randomisation service by telephone. The randomisation service allocated families to intervention or waiting list and informed the researcher of a trial number. The FLNP coordinators for the appropriate district (and not the researchers) were informed of the intervention or control status of families using a randomisation confirmation report.

- ***Blinding***

Videos and speech samples were coded by researchers who did not know the families and all data analyses were carried out blind to group allocation. The five minute speech samples were coded by researchers blind to whether the samples were pre intervention or at 9 months.

The participants and FLNP coordinators were not blind to allocation to intervention or waiting list control. The course facilitators did not know which parents were in the trial. The researchers were blind to intervention status initially, although some families did

disclose their assignment status when outcome measures were collected after the course.

- ***Statistical methods***

The primary analysis compares the change after 9 months (from baseline) of negative and supportive parenting in the FLNP with change after 9 months of negative and supportive parenting in the control group. In order to account for any lack of independence in the outcome variables attributable to group effects, attributable to families attending the same session and to families with more than one child, mixed models including a random course effect were used to make the comparisons.

Change for negative parenting was obtained by subtracting the 9 month negative parenting value from the baseline negative parenting value (baseline – month 9) while the change for supportive parenting was obtained by subtracting the baseline supportive parenting value from the 9 month supportive parenting value (month 9 – baseline). Because a higher value for negative means poorer parenting and a higher value of supportive parenting means better parenting, a positive difference thus corresponds to improvement in each case.

Similar mixed models were used for comparing the improvements for the secondary outcomes. The primary analysis for both the primary and secondary outcome measures was done on a treatment allocated basis.

A secondary analysis assessed the effect of the number of FLNP sessions attended. The analysis took the number of FLNP sessions attended in a continuous form and also after categorising the number of FLNP sessions attended (0, 1-4, 5-10). As in the primary analysis, mixed models are used for the secondary analysis and positive change scores indicate a benefit to parenting or wellbeing.

We analysed month 3 data using the same methods as the month 9 visit data for the three outcomes collected at the 3 month visit; PSI, WEMWEBS and PedQL. We used multi-level models (two levels for PSI and WEMWBS; parent and course level and three levels for PedQL; child, family and course levels) to test the impact of FLNP. We performed three sets of analyses; an treatment allocated analysis, the number of FLNP sessions attended as a continuous variable and in the third analysis we categorised the families into (1) No FLNP session (2) 1-4 sessions, and (3) 5-10 sessions.

Identification and measurement of costs

o Implementation Costs

The resources associated with implementation of FLNP were collected during 2009 from structured interviews with key staff at each of the four study sites, collection of financial information at each site (e.g. estimates of room hire and crèche facilities) and discussions with the main trial team. Implementation costs associated with the programme were estimated by multiplying resource usage by unit costs (where available) sourced from published 2009 PSSRU reference costs for health and social care [43] or from costs provided during interviews. The main cost categories established

included staff (facilitator) and administration costs, training; venue hire, crèche provision and course materials/refreshments. Due to variability within and between each study site on staffing arrangements (e.g. grade and mix of staff used to deliver FLNP programmes), costs were separately estimated for each site and the mean cost per programme and per family attending derived from these estimates.

- ***Parental resources***

Parental resource utilisation was collected from parents using a specifically designed questionnaire. This was undertaken at the 9 month follow up as part of a structured interview administered by the researcher at each study site. Data was collected on: FLNP (number of attendances at each course, number of people (on average) in each group; attendance on other parenting programmes (including programme name, number of sessions attended, length and type of session, number of people in each group); Other parenting contacts e.g. Health Visitor/nursery nurse other groups, Psychologist, obtaining books/watching TV programmes/Internet support and costs of attending programme (travel, time off work, other out-of pocket expenses e.g. child minding costs).

Parent participation time was calculated using number of sessions attended multiplied by session duration, while parent travel time was identified by multiplying the available data on numbers of sessions attended walking, using public travel, taxi, own car or a lift by estimated times of travel. In order to achieve this, assumptions were made that parents would walk at 3 mph if sessions were one mile or less away from their home (supported by data) and that a car journey was made at 30 mph average speed. For a

taxi journey and a lift 5 minutes waiting time was added and for public travel 10 minutes were added for waiting time and additional bus stops. Costs for travel (public, taxi and lift) were collected during the trial, while costs of using an owned car was calculated by multiplying the miles driven to get to sessions by the HM Revenue & Customs recommended mileage rate 2002/03 – 2010/11 [54] of 0.40 pence per mile. It was assumed that walking did not incur any financial cost.

Unit costs were applied to parent participation time employing the human capital approach [55]. The value of work, as well as leisure time, was estimated by applying hourly rates - according to the parents' professions - to the time expended on the FLNP programme, travel and other programmes attended [56]. Hourly rates of household/domestic help were used to cost time of unemployed parents.

- ***Costs of health, social care, education, criminal justice and voluntary services***

Contacts with other services were collected as part of the questionnaire described above. Unit costs of contacts with social services, educational psychology and criminal justice system, and use of voluntary services were identified from discussions with Professor Martin Knapp and his research team at PSSRU and from PSSRU reference costs for health and social care [43].

Health economic methods

- ***Cost consequences analysis***

A cost consequences analysis (CCA) was undertaken to provide a description of the cost of achieving the differences between FLNP and control group observed in the statistical analyses for each outcome measure. The CCA was undertaken from a 9-month time perspective to reflect the timescale of the trial.

- ***Cost-utility analysis***

Utility estimates (Quality Adjusted Life Years (QALYs)) were derived from the SF-6D data collected on parents at baseline and 9 months. Lack of suitable measures from which to calculate QALY gain in children precluded inclusion of this key aspect of the cost utility. The first analysis was based on cases with complete data (missing cases excluded) and the second on all available cases estimating missing values using mean imputation. The cost per QALY gained as a result of the FLNP was estimated using 5 and 10-year time horizons. The underlying assumption was that the utility gain/loss over the 9 months of the trial would be translated into a 12 month QALY gain, and then remain constant over the remaining years of the extrapolation for the 5 and 10-year estimates. Discount rates of 3.5% p.a. were applied to costs.

A series of sensitivity analyses were undertaken to determine the impact of adjusting parameter estimates relating to costs in order to present a series of different cost

scenarios. Further, a probabilistic sensitivity analysis was undertaken to assess the extent to which the cost-effectiveness of the FLNP lies within thresholds of what is regarded as representing value for money – that is cost per QALY estimates of less than £20,000 or in some cases up to £30,000.

Qualitative methods

Interviews were transcribed in full and examined for responses that addressed the pre-specified themes. Quotations were extracted relevant to each theme and grouped into similar responses. Quotations were selected to illustrate each group of responses.

Other Methods

- ***Coding of five minute speech samples and videos of parent-child interation***

Speech samples were coded following training of researchers by the programme developer according to the developer's manuals. Coding was undertaken by researchers blind to group allocation of the families. Video coding was undertaken in the same manner.

- ***Programme fidelity***

A senior practitioner from Family Links viewed recordings of three random sessions from each course attended by parents on the trial and coded them against 9 criteria. Fidelity measures the extent to which the programme was delivered as the programme developers intend. Three sessions were recorded for each programme. The senior practitioner viewed one of these for each programme selected at random and if there were any concerns she viewed the other two sessions. She also examined practitioner and participant evaluation forms and the family logs where possible.

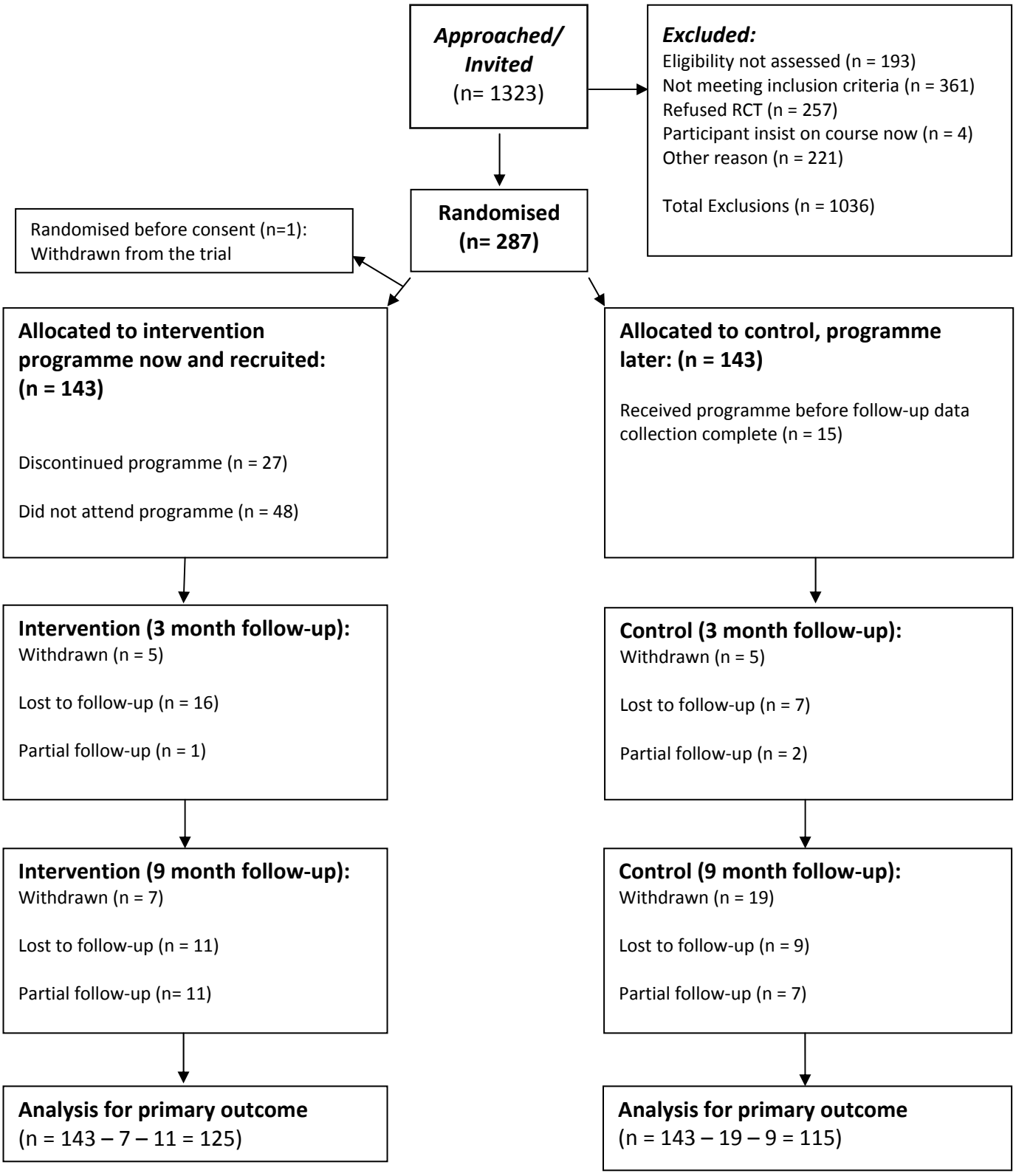
Uptake rates; attendance rates (number of sessions attended); dropout rates; mother/father ratio of attendees and attendance and dropout by day and time of group were measured.

- **Data quality assurance**

10% of all data for each outcome variable were checked and if any transcription errors were identified, 100% of that data field was checked.

Chapter 3: Results

Figure 1 the CONSORT Flowchart



Recruitment

Approximately 1323 families were identified as potentially eligible to take part in the trial and approached by FSP staff. The precise methods of identification and approach varied in different areas. In some areas parents were invited to a coffee morning, in others parents were approached individually when they attended the FS centres. Parents were also approached by Health Visitors in their own homes, and by staff at children's playgroups and schools. Of families approached 27% (286) were recruited; two short of the planned sample size of 288. One parent was mistakenly randomised before consent, so the consort flowchart shows a total of 287 families randomised. Recruitment took place over five school terms and four county councils rather than the planned two terms and three county councils [57]. The key factors in slow recruitment were delays in the Research and Development approval process, an initial ambivalence to recruitment from practitioners and the fact that as the group-based intervention operated in term times, there were only three opportunities for recruitment each year. Successful recruitment strategies were developed with local managers and tailored to each site and recruitment improved during the trial [57]. Table 1 shows recruitment by phase and site. Retention in the trial was very good - 89% at 3 months and 84% at 9 months, exceeding estimations in the protocol (80%). The lowest retention rate in any phase was 77% at 9 months in phase 3.

The requirement to make a video of parent-child interaction during the child's mealtime and the demands which the trial would make on parent's time were the most common reasons given for deciding not to take part in the research. To boost recruitment, the

trial team took the decision to make the video recording optional. These data are therefore only available on two thirds of the sample. Further results relating to recruitment are addressed in the qualitative analysis results on page 65.

Attendance at the programme

Of the 143 families randomised and recruited to attend the programme, 48 (34%) did not attend any sessions and a further 27 (19%) discontinued the programme in the first few sessions. Amongst the 143 allocated to the control group 15 (10%) had attended a FLNP before the 9 month follow up was complete. Data on service use by parents during the trial gathered for health economic analyses show a further 13 (9%) control group parents had attended other parenting support programmes in the locality during the course of the trial, as had one FLNP group parent.

Table 1. FLNP Recruitment by Phase and Site

	Phase 1	**Phase 2**	**Phase 3**	**Phase 4**	**Phase 5**	**Total**
Caerphilly	N/A	4	5	12	17	38
Cardiff	10	20	28	20	11	89
Newport	3	25	15	35	5	83
Torfaen	11	13	21	21	10	76
Total	24	62	69	88	43	286

Baseline data

Table 2 shows the baseline characteristics of the families recruited to the trial. Because some children were siblings and because only one parent was followed up in each family, there are two more children in the control group and seven more children in the FLNP group than parents. The distribution of characteristics (gender, working parents, ethnicity and parents' education) suggest that randomisation was effective. Parenting scores were similar in both groups.

- ***Numbers analysed***

The primary analysis compares the changes in the FLNP group to the changes in the control group using a treatment allocated analysis. For the primary outcomes, data were available on 249 children and 240 parents as there were nine sibling pairs. Of the 249 children, only 221 (214 families) had complete data. Two sets of analysis were performed to address the issue of missing data. In the first set of analyses, only cases with complete data were included (complete case analysis (115 children / 110 parents in the FLNP arm and 106 / 104 in the control arm). In the second set of analyses, missing values were imputed for items in questionnaires that had partial data. The results for the two sets of analyses are similar and in this report we present results for the complete case analysis only.

Table 2 Baseline characteristics of families

Characteristic	Control	FLNP
No. of parents	143	143
No. of children	145	150
Negative parenting: Mean (sd)	11.07 (10.20)	10.61 (11.36)
Supportive parenting: Mean (sd)	26.00 (2.64)	25.88 (2.92)
Parent gender: n (%) of females	139 (99.3)	136 (95.1)
No. of parents with partner: n (%)	49 (34.3)	46 (32.4)
Parent working: n (%) working	112(78.3)	112 (78.9)
Parent's ethnicity: n (%)		
White British	103 (72.0)	100 (69.9)
White other	21 (14.7)	22 (15.4)
Black African	4 (2.8)	0
Black Caribbean	0	1 (0.7)
Asian Indian/Pakistan/Bangladeshi	9 (6.3)	6 (4.2)
Asian Chinese	0	2 (1.4)
Other	6 (4.2)	12 (8.4)
Parent's education: n (%)		
NVQ	26 (18.4)	28 (20.1)
GCSE / O levels	46 (32.6)	39 (28.1)
A levels	16 (11.3)	15 (10.8)
Degree	17 (12.1)	15 (10.8)
Higher degree	4 (2.8)	3 (2.2)
None	24 (17.0)	24 (17.3)
Other	8 (5.7)	15 (10.8)

- ***Outcomes and estimation***

Figure 2 shows histograms for the change in negative parenting scores by group (FLNP or control). Scores in both groups improved and in both the improvements were approximately normally distributed. The mean improvement for the control group was 1.351 and the standard deviation 8.34. The mean improvement for the FLNP group was 2.230 and the standard deviation 10.79. There is slightly more improvement in the FLNP group than the control group.

Figure 2. Histograms of improvement of negative parenting by group

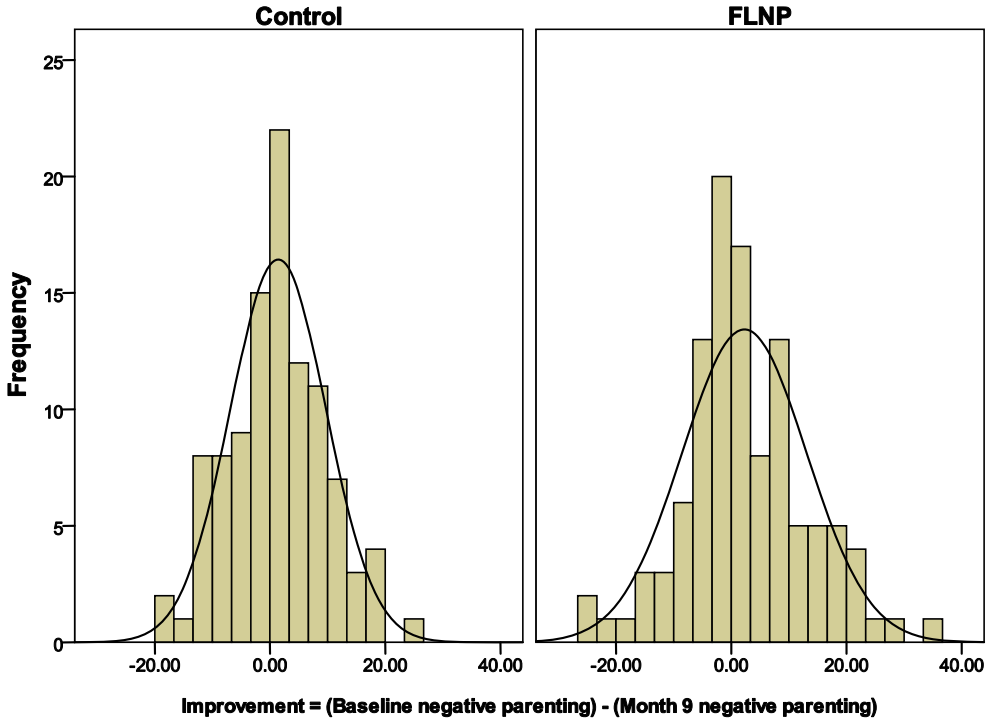
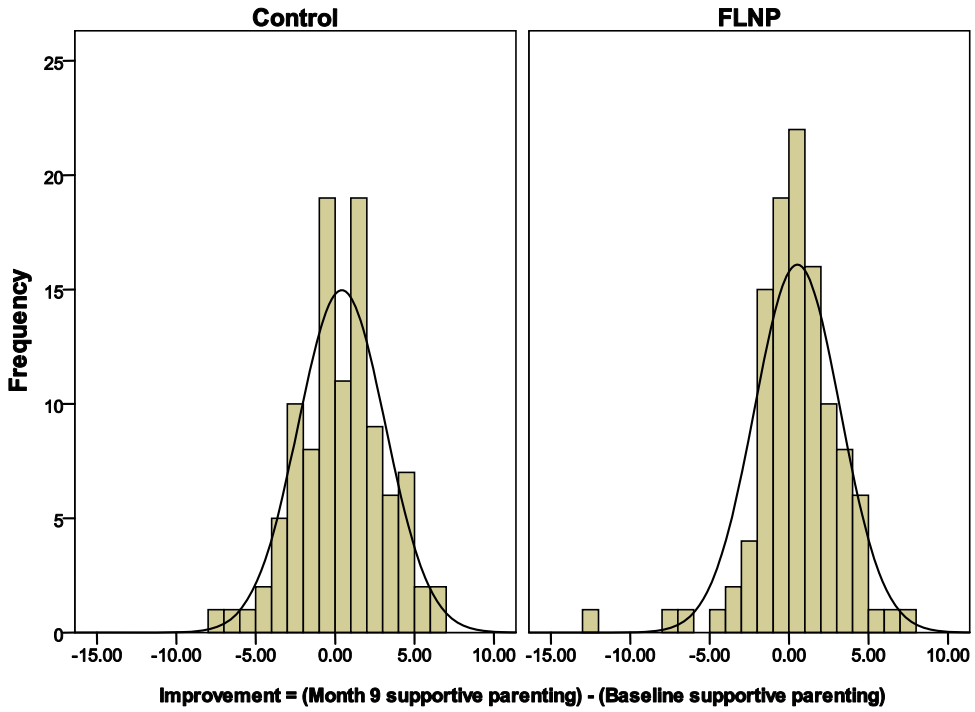


Figure 3 shows changes in supportive parenting by group. Here again both groups improved and the improvements are approximately normally distributed. The mean improvement for the control group was 0.431 and the standard deviation 2.76. The mean improvement for the FLNP group was 0.522 and the standard deviation was 2.70. The FLNP group shows slightly more improvement in supportive parenting than the control group.

Figure 3. Histograms of improvement of supportive parenting by group



Primary analysis results

The 221 child cases and 214 parent cases with complete data were analysed on a treatment allocated basis. To allow for possible correlation between responses from participants on the same course, we used mixed effects models to compare the changes in outcomes for parents randomised to the control and FLNP groups. Table 3 shows the results of multi-level models used to test the effect of the FLNP on both primary and the majority of secondary outcome measures. Table 3a presents the same analyses for changes in parent child interaction in the child meal time video.

Both primary outcomes changed in a positive direction in both FLNP and control groups. Although the change in negative parenting was significant in the FLNP and not in the

control group there was no significant difference when the change in one group was compared to that in the other. This pattern of results was repeated for supportive parenting and for ten out of the sixteen secondary outcomes. Three of the outcomes favouring the control group were from the PrePACs measure, one from the five minute speech sample, one from the meal time video. The final measure favouring the control group was a parent wellbeing measure (Parenting Stress Index). A further analysis using imputation for the missing data (not reported in detail here) gave similar p-values with the differences between the control and FLNP remaining statistically insignificant.

Table 3: Summary of parameter estimates for mixed effects models

Outcome/parameter	Estimate	Std Error	p-value	95% Confidence interval
Negative parenting				
Control	1.4127	0.9550	0.141	(-0.4698, 3.2953)
FLNP	2.3094	1.0234	0.032	(0.2107, 4.4082)
Difference	0.8967	1.3997	0.524	(-1.8950, 3.6884)
Supportive parenting				
Control	0.3828	0.2693	0.157	(-0.1482, 0.9137)
FLNP	0.5480	0.2759	0.060	(-0.0249, 1.1209)
Difference	0.1652	0.3856	0.670	(-0.6054, 0.9358)
Parenting Stress Index				
Control	5.8788	1.7784	0.001	(2.3723, 9.3853)
FLNP	5.0814	1.7214	0.007	(1.5117, 8.6511)
Difference	-0.7974	2.4751	0.748	(-5.7351, 4.1403)
PedQL				
Control	-0.1986	0.8077	0.806	(-1.7905, 1.3933)
FLNP	1.2983	0.7993	0.106	(-0.2770, 2.8736)
Difference	1.4970	1.1363	0.189	(-0.7426, 3.7365)
WEMWBS				
Control	2.5310	0.8054	0.002	(0.9441, 4.1178)
FLNP	3.0227	0.8250	0.002	(1.2912, 4.7542)
Difference	0.4917	1.1530	0.671	(-1.8181, 2.8016)

Outcome/parameter	Estimate	Std Error	p-value	95% Confidence interval
Hyperactivity scale (weekly)				
Control	2.5734	0.6641	<0.001	(1.2651, 3.8817)
FLNP	3.4299	0.6295	<0.001	(2.1896, 4.6702)
Difference	0.8565	0.9151	0.350	(-0.9462, 2.6593)
Hyperactivity scale (Typical)				
Control	2.6165	0.6887	<0.001	(1.2597, 3.9734)
FLNP	2.5829	0.8207	0.005	(0.8845, 4.2812)
Difference	-0.0336	1.0713	0.975	(-2.1833, 2.1160)
Conduct scale (weekly)				
Control	1.2343	0.8340	0.140	(-0.4088, 2.8774)
FLNP	1.2655	1.0047	0.217	(-0.7800, 3.3110)
Difference	0.0312	1.3058	0.981	(-2.5735, 2.6360)
Conduct scale (Typical)				
Control	1.4971	0.7847	0.058	(-0.0489, 3.0430)
FLNP	1.3775	0.8793	0.129	(-0.4310, 3.1860)
Difference	-0.1196	1.1785	0.920	(-2.4742, 2.2351)
Internalising scale (Freg)				
Control	0.2631	0.3336	0.431	(-0.3944, 0.9206)
FLNP	0.3947	0.3424	0.261	(-0.3129, 1.1023)
Difference	0.1316	0.4781	0.784	(-0.8226, 1.0858)
Internalising scale (Reassure)				
Control	0.3933	0.4225	0.353	(-0.4392, 1.2257)
FLNP	0.1032	0.3983	0.796	(-0.6818, 0.8881)
Difference	-0.2901	0.5806	0.618	(-1.4343, 0.8541)
5 MinuteSpeech Sample warmth of initial statement				
Control	0.2895	0.1420	0.043	(0.0096, 0.5694)
FLNP	0.2982	0.1379	0.041	(0.0129, 0.5836)
Difference	0.0087	0.1980	0.965	(-0.3859, 0.4034)
5 minute speech sample % negative comments				
Control	0.0649	0.0305	0.034	(0.0049,0.1250)
FLNP	0.0515	0.0291	0.078	(-0.0058,0.1088)
Difference	-0.0134	0.0421	0.751	(-0.0964,0.0697)

Table 3a: Summary of parameter effects for missed effects model: As allocated analysis: Child Mealtime Video

Outcome/parameter	Estimate	Std Error	p-value	95% Confidence interval
Proportion of negative interactions				
Control	-0.0175	0.0214	0.415	(-0.0597, 0.0247)
FLNP	0.0283	0.0213	0.185	(-0.0137, 0.0703)
Difference	0.0458	0.0301	0.131	(-0.0137, 0.1053)
Rate of negative interactions (Length)				
Control	-0.0213	0.1039	0.838	(-0.2265, 0.1839)
FLNP	0.0878	0.1021	0.391	(-0.1138, 0.2894)
Difference	0.1091	0.1457	0.455	(-0.1786, 0.3968)
Rate of positive interactions (Length)				
Control	-0.1373	0.4638	0.768	(-1.0529, 0.7784)
FLNP	0.6166	0.4558	0.178	(-0.2831, 1.5164)
Difference	0.7539	0.6503	0.248	(-0.5298, 2.0376)
Rate of negative interactions (Involvement)				
Control	-0.1854	0.1907	0.333	(-0.5624, 0.1916)
FLNP	-0.1549	0.1920	0.421	(-0.5344, 0.2247)
Difference	0.0306	0.2706	0.910	(-0.5044, 0.5655)
Rate of positive interactions (Involvement)				
Control	0.9248	1.0094	0.361	(-1.0708, 2.9204)
FLNP	2.5470	1.0127	0.013	(0.5441, 4.5498)
Difference	1.6221	1.4299	0.259	(-1.2051, 4.4494)

Secondary analysis

A secondary analysis was performed based on treatment received adjusting for the number of FLNP sessions attended. 48 parents who were recruited and randomised to the FLNP arm did not attend the programme at all. Also, some parents who were randomised to the FLNP arm did not attend all the scheduled FLNP sessions. In the

control arm, 15 parents (11 complete cases) received the FLNP programme before they completed the 9 month follow-up. All parents from either group who did not attend the FLNP are included in the 0 attendance group and all parents from either group who attended one or more sessions are included in the relevant category of attendees. In these analyses therefore the benefits of randomisation are lost.

Figure 4 shows the scatter plot of the number of FLNP sessions attended before 9 month follow-up data were collected against the changes in negative parenting after 9 months. The total number of FLNP sessions on the course is 10.

Figure 4: Scatter plot for the number of FLNP sessions attended against changes in the negative parenting at month 9.

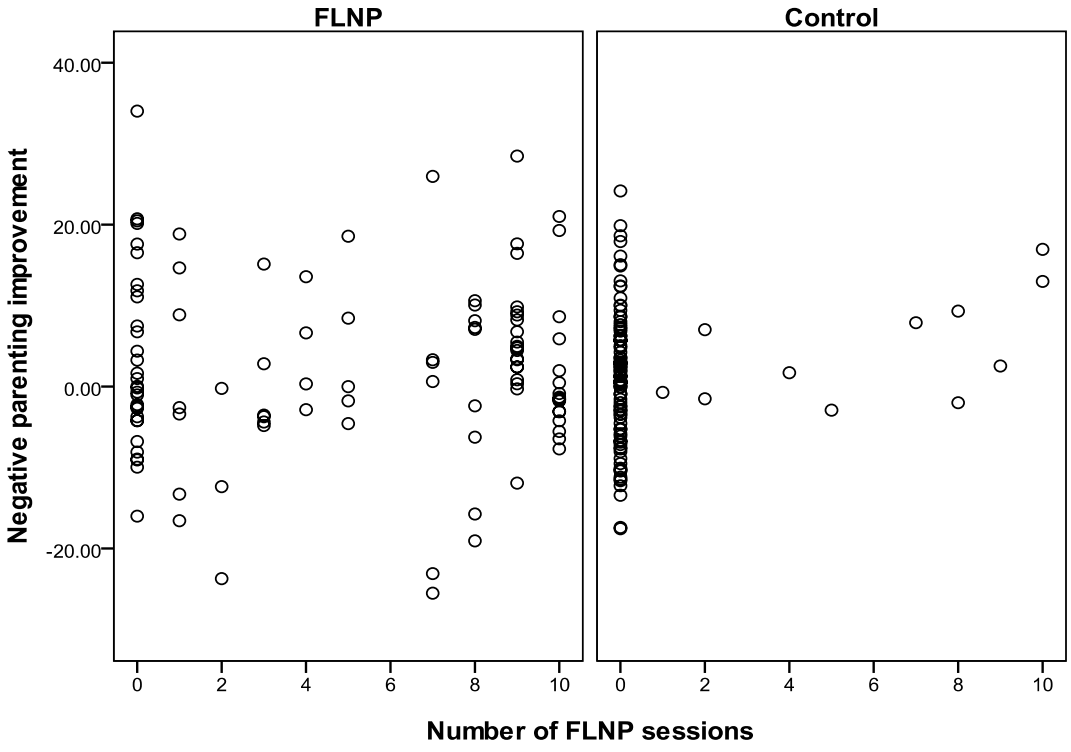
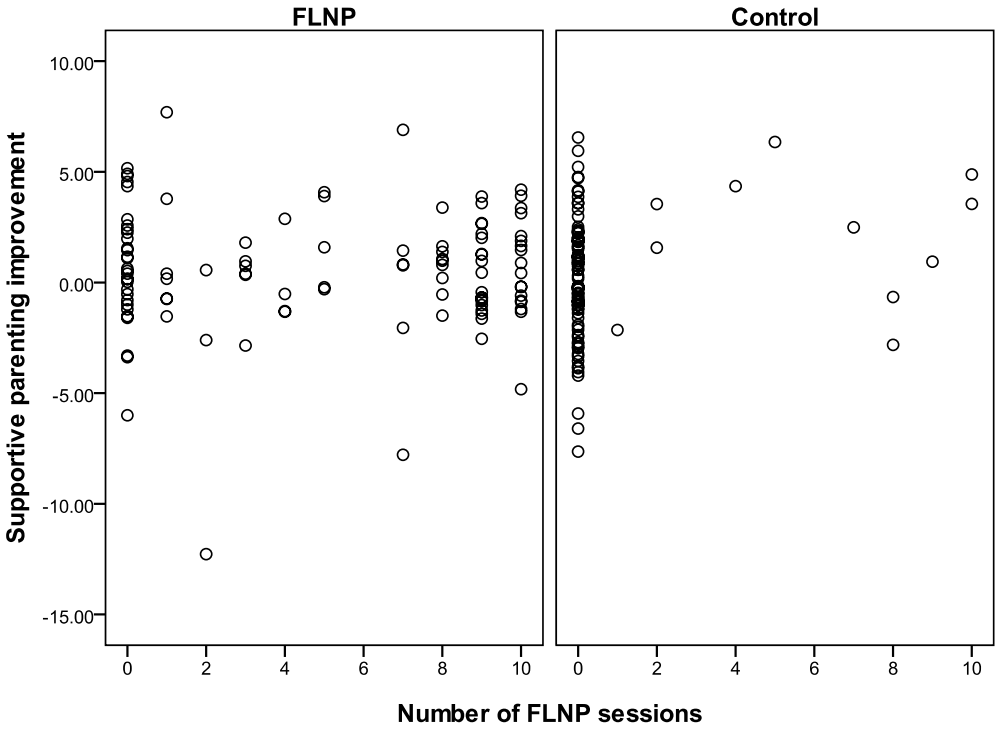


Figure 5 shows the scatter plot of the number of FLNP sessions attended before month 9 follow-up data were collected against the changes in supportive parenting after 9 months.

Figure 5: Scatter plot for the number of FLNP sessions attended against the supportive parenting improvement at month 9.



- ***Results of secondary analysis***

Table 4 shows the results of multi-level models fitted assuming a linear effect of the number of FLNP sessions attended. Table 4a shows the same results for change in parent-child interaction during the mealtime video. The "Intercept" corresponds to the improvement for parents who did not attend a FLNP session and the "Session" is the estimated change observed in that outcome for each extra session attended (assuming

that change was linear). For negative parenting, the fitted change for parents who did not attend a FLNP session is 1.2845, a non-significant improvement. The fitted change for negative parenting when a parent attends an extra session is 0.2098, another non – significant improvement. This pattern is repeated for supportive parenting and all but three of secondary outcomes. Among the latter, a borderline significant improvement was found for the PrePACS Hyperactivity scale (weekly), with an estimated improvement for each session attended of 0.2153 (p = 0.064). This was balanced by a non-significant result favouring the control group on the two PrePACs internalising scales and one of the mealtime video scores. For all but one of the outcomes where a greater improvement was shown in the control group in the 'treatment as allocated' analysis, presented in table 3 (Parenting Stress Index, PrePACS, Hyperactivity scale (Typical), Conduct scale (Typical) and Speech Sample % negative comments) the direction of change has reversed with results now favouring parents attending the FLNP. None of these results are statistically significant.

Table 4: Summary of parameter estimates for mixed effect models with continuous number of FLNP sessions attended

Outcome/parameter	Complete case analysis			
	Estimate	**Std Error**	**p-value**	**95% Confidence interval**
Negative parenting				
Intercept	1.2845	0.8268	0.122	(-0.3468, 2.9159)
Session	0.2098	0.1719	0.224	(-0.1297, 0.5492)
Supportive parenting				
Intercept	0.3024	0.2321	0.194	(-0.1557, 0.7605)
Session	0.0591	0.0483	0.223	(-0.0362, 0.1544)
Improvement in Parenting Stress Index				
Intercept	4.5433	1.5213	0.003	(1.5437, 7.5430)
Session	0.3298	0.3178	0.301	(-0.2968, 0.9563)

Outcome/parameter	Complete case analysis			
	Estimate	Std Error	p-value	95% Confidence interval
PedQL				
Intercept	0.1917	0.7045	0.786	(-1.1967, 1.5801)
Session	0.1258	0.1426	0.379	(-0.1553, 0.4070)
WEMWBS				
Intercept	2.2355	0.6944	0.002	(0.8655, 3.6056)
Session	0.1977	0.1433	0.169	(-0.0851, 0.4805)
Hyper activity scale (Weekly)				
Intercept	2.4094	0.5626	<0.001	(1.3012, 3.5177)
Session	0.2153	0.1159	0.064	(-0.0130, 0.4436)
Hyperactivity scale (Typical)				
Intercept	2.5132	0.6036	<0.001	(1.3223, 3.7041)
Session	0.0396	0.1244	0.750	(-0.2058, 0.2850)
Conduct scale (Weekly)				
Intercept	0.7795	0.7336	0.289	(-0.6670, 2.2260)
Session	0.1993	0.1516	0.190	(-0.0994, 0.4981)
Conduct scale (Typical)				
Intercept	1.1467	0.6846	0.096	(-0.2033, 2.4968)
Session	0.1199	0.1426	0.402	(-0.1615, 0.4013)
Internalising scale (Freq)				
Intercept	0.3617	0.2887	0.212	(-0.2080, 0.9314)
Session	-0.0127	0.0596	0.832	(-0.1303, 0.1050)
Internalising scale (Reassure)				
Intercept	0.5923	0.3563	0.098	(-0.1098, 1.2943)
Session	-0.1241	0.0735	0.093	(-0.2690, 0.0207)
5 Minute Speech Sample warmth of opening statement				
Intercept	0.2429	0.1222	0.048	(0.0020, 0.4839)
Session	0.0174	0.0244	0.478	(-0.0309, 0.0657)
5 Minute Speech Sample % negative comments				
Intercept	0.0344	0.0263	0.193	(-0.0176,0.0864)
Session	0.0078	0.0052	0.136	(-0.0025, 0.0181)

Table 4a: Summary of parameter effects for missed effects model: Child Mealtime Video Taking the number of FLNP sessions as continuous

Outcome/parameter	Estimate	Std Error	p-value	95% Confidence interval
Proportion of negative interactions				
Intercept	-0.0055	0.0194	0.778	(-0.0437, 0.0328)
Session	0.0034	0.0037	0.363	(-0.0039, 0.0107)
Rate of negative interactions (Length)				
Intercept	0.0043	0.0935	0.963	(-0.1802, 0.1888)
Session	0.0090	0.0177	0.610	(-0.0259, 0.0440)
Rate of positive interactions (Length)				
Intercept	0.0054	0.4199	0.990	(-0.8237, 0.8345)
Session	0.0583	0.0818	0.477	(-0.1034, 0.2201)
Rate of negative interactions (Involvement)				
Intercept	-0.1938	0.1751	0.270	(-0.5400, 0.1524)
Session	0.0069	0.0328	0.833	(-0.0579, 0.0718)
Rate of positive interactions (Involvement)				
Intercept	2.2744	1.1036	0.042	(0.0828, 4.4659)
Session	-0.0236	0.0981	0.811	(-0.2197, 0.1724)

Table 5 shows the analysis after categorising the number of FLNP sessions attended into: those parents who did not attend a FLNP session (No FLNP session), those parents that attended between one and four FLNP sessions (1 to 4 sessions), and those parents who attended 5 or more FLNP sessions (5-10 sessions). Table 5a shows the same results for the mealtime video analysis "Difference (1-4)" shows the estimated benefit of attending between 1 and 4 FLNP sessions over not attending a session. A positive

estimate indicates that attending between 1 and 4 sessions shows more improvement than not attending any sessions while a negative estimate indicates that not attending a FLNP session leads to more improvement than attending between 1 and 4 FLNP sessions. “Difference (5-10)” shows the estimated difference between not attending any FLNP sessions and attending 5 or more FLNP sessions with a positive value indicating there is more improvement if a parent attends 5 or more sessions than if he/she does not attend a session.

For both primary outcomes, negative parenting and supportive parenting, changes among parents attending 1-4 sessions were less than among parents attending no sessions. This was also true of two of the six PrePACs scales (Conduct (weekly) and Internalising (reassure)) and two of the mealtime video scores.

For parents attending more than 5 programme sessions all results bar three PrePACs scale items (Internalising (freq) and Internalising (reassure)) and mealtime video outcome favoured parents attending the FLNP. The improvement in the PrePACS Hyperactivity scale (weekly) for parents attending more than 5 programme sessions (2.3272) was significantly greater than that for those attending no sessions (p=0.02).

Table 5: Summary of parameter estimates for mixed effects models with the number of FLNP sessions attended categorised into 3 categories

Outcome/parameter	Complete case analysis			
	Estimate	**Std Error**	**p-value**	**95% Confidence interval**
Improvement in negative parenting				
No FLNP session	1.5767	0.8739	0.073	(-0.1466, 3.2300)
1 – 4 FLNP sessions	0.2287	1.9692	0.908	(-3.6570, 4.1143)
5 – 10 FLNP sessions	3.0583	1.2582	0.018	(0.5502, 5.5665)
Difference (1-4)	-1.3481	2.1400	0.529	(-5.5670, 2.8709)
Difference (5-10)	1.4816	1.5128	0.329	(-1.5056, 4.4689)
Improvement in supportive parenting				
No FLNP session	0.2928	0.2459	0.235	(-0.1920, 0.7775)
1 – 4 FLNP sessions	0.2544	0.5525	0.646	(-0.8360, 1.3448)
5 – 10 FLNP sessions	0.9010	0.3507	0.012	(0.2008, 1.6012)
Difference (1-4)	-0.0384	0.6021	0.949	(-1.2254, 1.1486)
Difference (5-10)	0.6083	0.4247	0.154	(-0.2306, 1.4471)
Improvement in Parenting stress index				
No FLNP session	4.2083	1.6137	0.010	(1.0265, 7.3901)
1 – 4 FLNP sessions	6.5652	3.6859	0.076	(-0.7025, 13.8329)
5 – 10 FLNP sessions	7.5000	2.2450	0.001	(3.0734, 11.9266)
Difference (1-4)	2.3569	4.0236	0.559	(-5.5768, 10.2906)
Difference (5-10)	3.2917	2.7647	0.235	(-2.1598, 8.7431)
PedsQL				
No FLNP session	0.1468	0.7462	0.844	(-1.3240, 1.6175)
1 – 4 FLNP sessions	1.2174	1.7759	0.494	(-2.2825, 4.1173)
5 – 10 FLNP sessions	1.1100	1.0222	0.279	(-0.9047, 3.1247)
Difference (1-4)	1.0706	1.9263	0.579	(-2.7258, 4.8670)
Difference (5-10)	0.9632	1.2656	0.447	(-1.5312, 3.4576)
Improvement in WEMWBS score				
No FLNP session	2.3225	0.7362	0.002	(0.8713, 3.7737)
1 – 4 FLNP sessions	2.3400	1.6569	0.159	(-0.9282, 5.6082)
5 – 10 FLNP sessions	3.8832	1.0396	<0.001	(1.8061, 5.9603)
Difference (1-4)	0.0175	1.8054	0.992	(-3.5401, 3.5750)
Difference (5-10)	1.5607	1.2632	0.218	(-0.9331, 4.0544)
Improvement in Hyperactivity scale (Weekly)				
No FLNP session	2.0867	0.5947	0.001	(0.9152, 3.2582)
1 – 4 FLNP sessions	4.0741	1.3462	0.003	(1.4222, 6.7260)
5 – 10 FLNP sessions	**4.4139**	**0.8172**	**<0.001**	**(2.8037, 6.0241)**
Difference (1-4)	1.9873	1.4717	0.178	(-0.9118, 4.8865)

Outcome/parameter	Complete case analysis			
	Estimate	**Std Error**	**p-value**	**95% Confidence interval**
Difference (5-10)	2.3272	1.0107	**0.022**	(0.3359, 4.3184)
Improvement in Hyperactivity scale (Typical)				
No FLNP session	2.4449	0.6325	<0.001	(1.1979, 3.6919)
1 – 4 FLNP sessions	3.9315	1.4500	0.007	(1.0739, 6.7890)
5 – 10 FLNP sessions	2.4925	0.9520	0.011	(0.5978, 4.3871)
Difference (1-4)	1.4866	1.5466	0.337	(-1.5600, 4.5332)
Difference (5-10)	0.0476	1.0956	0.965	(-2.1137, 2.2089)
Improvement in Conduct scale (Weekly)				
No FLNP session	0.9179	0.7450	0.231	(-0.5898, 2.4256)
1 – 4 FLNP sessions	-0.0025	1.7595	0.999	(-3.4693, 3.4643)
5 – 10 FLNP sessions	2.6007	1.1647	0.028	(0.2916, 4.9097)
Difference (1-4)	-0.9204	1.8744	0.624	(-4.6128, 2.7720)
Difference (5-10)	1.6828	1.3356	0.209	(-0.9505, 4.3161)
Hyperactivity in Conduct scale (Typical)				
No FLNP session	1.1590	0.7189	0.108	(-0.2579, 2.5759)
1 – 4 FLNP sessions	2.1692	1.6557	0.192	(-1.0941, 5.4324)
5 – 10 FLNP sessions	1.8479	1.0715	0.088	(-0.2845, 3.9802)
Difference (1-4)	1.0102	1.7782	0.570	(-2.4926, 4.5130)
Difference (5-10)	0.6889	1.2544	0.584	(-1.7862, 3.1640)
Internalising (Freq)				
No FLNP session	0.3784	0.3060	0.218	(-0.2249, 0.9818)
1 – 4 FLNP sessions	0.6123	0.6882	0.375	(-0.7453, 1.9700)
5 – 10 FLNP sessions	0.1072	0.4352	0.806	(-0.7606, 0.9750)
Difference (1-4)	0.2339	0.7484	0.755	(-1.2411, 1.7089)
Difference (5-10)	-0.2712	0.5260	0.607	(-1.3099, 0.7675)
Internalising (Reassure)				
No FLNP session	0.6598	0.3764	0.081	(-0.0819, 1.4016)
1 – 4 FLNP sessions	-0.1250	0.8965	0.889	(-1.8914, 1.6414)
5 – 10 FLNP sessions	-0.4456	0.5217	0.394	(-1.4739, 0.5828)
Difference (1-4)	-0.7848	0.9723	0.420	(-2.7006, 1.1309)
Difference (5-10)	-1.1054	0.6433	0.087	(-2.3733, 0.1625)
5 Minute Speech Sample warmth of initial statement				
No FLNP session	0.2062	0.1298	0.114	(-0.0496, 0.4620)
1 – 4 FLNP sessions	0.4227	0.2873	0.143	(-0.1440, 0.9893)
5 – 10 FLNP sessions	0.4078	0.1741	0.023	(0.0593, 0.7563)
Difference (1-4)	0.2164	0.3146	0.492	(-0.4035, 0.8364)
Difference (5-10)	0.2016	0.2162	0.353	(-0.2255, 0.6287)

Outcome/parameter	Complete case analysis			
	Estimate	Std Error	p-value	95% Confidence interval
5 Minute Speech Sample % negative comments				
No FLNP session	0.0333	0.0281	0.237	(-0.0220, 0.0887)
1 – 4 FLNP sessions	0.0676	0.0623	0.280	(-0.0555, 0.1906)
5 – 10 FLNP sessions	0.0997	0.0373	0.011	(0.0241, 0.1753)
Difference (1-4)	0.0342	0.0683	0.617	(-0.1004, 0.1688)
Difference (5-10)	0.0664	0.0465	0.157	(-0.0259, 0.1586)

Table 5a: Summary of parameter effects for missed effects model: Child Mealtime Video : Categorised the number of sessions attended into three categories

Outcome/parameter	Estimate	Std Error	p-value	95% Confidence interval
Proportion of negative interactions				
No FLNP session	-0.0083	0.0204	0.684	(-0.0487, 0.0320)
1 – 4 FLNP sessions	0.0136	0.0463	0.769	(-0.0778, 0.1051)
5 – 10 FLNP sessions	0.0255	0.0260	0.329	(-0.0260, 0.0769)
Difference (1-4)	0.0220	0.0506	0.665	(-0.0780, 0.1220)
Difference (5-10)	0.0338	0.0331	0.308	(-0.0315, 0.0992)
Rate negative interactions (Length)				
No FLNP session	-0.0095	0.0986	0.923	(-0.2042, 0.1851)
1 – 4 FLNP sessions	0.1122	0.2253	0.619	(-0.3325, 0.5569)
5 – 10 FLNP sessions	0.0801	0.1244	0.520	(-0.1655, 0.3258)
Difference (1-4)	0.1217	0.2459	0.621	(-0.3637, 0.6072)
Difference (5-10)	0.0897	0.1587	0.573	(-0.2237, 0.4031)
Rate positive interactions (Length)				
No FLNP session	0.1496	0.4399	0.734	(-0.7189, 1.0181)
1 – 4 FLNP sessions	-0.6474	1.0119	0.523	(-2.6455, 1.3507)
5 – 10 FLNP sessions	0.5033	0.6012	0.405	(-0.6915, 1.6982)
Difference (1-4)	-0.7970	1.0925	0.467	(-2.9537, 1.3597)
Difference (5-10)	0.3537	0.7329	0.630	(-1.0954, 1.8029)
Rate of negative interactions (Involvement)				
No FLNP session	-0.2142	0.1850	0.249	(-0.5798, 0.1515)
1 – 4 FLNP sessions	-0.1309	0.4191	0.755	(-0.9596, 0.6977)
5 – 10 FLNP sessions	-0.1155	0.2273	0.612	(-0.5649, 0.3338)
Difference (1-4)	0.0986	0.2930	0.737	(-0.4807, 0.6779)
Difference (5-10)	0.0832	0.4581	0.856	(-0.8225, 0.9890)
Rate of positive interactions (Involvement)				

Outcome/parameter	Estimate	Std Error	p-value	95% Confidence interval
No FLNP session	2.2324	1.1119	0.047	(0.0251, 4.4397)
1 – 4 FLNP sessions	2.3195	1.4825	0.120	(-0.6115, 5.2505)
5 – 10 FLNP sessions	2.1772	1.2937	0.095	(-0.3812, 4.7356)
Difference (1-4)	0.0871	1.1684	0.941	(-2.2507, 2.4249)
Difference (5-10)	-0.0553	0.9134	0.952	(-1.8815, 1.7710)

Summary of the results of secondary analysis

These secondary analyses have assessed the effect of the number of FLNP sessions attended by taking the number of FLNP sessions attended in the continuous form and also after categorising the number of FLNP sessions attended. With the exception of the two internalising PrePACs items, parenting and wellbeing scores improve among parents attending 5 or more sessions. In this group, statistically significant improvements were found in PrePACS Hyperactivity scale (weekly) but in no other endpoints. Results for parents attending 1-4 sessions were mixed.

Outcomes at three months

A limited set of data were gathered immediately after the programme finished on both control and intervention groups using a postal questionnaire. The questionnaire included two self-report parent wellbeing measures (WEMWBS and PSI) and one child outcome measure PedQL.

Table 6 shows the results of the allocated treatment analysis for these three month outcomes. The pattern of results mirrors those for the nine month outcomes with more change in the FLNP than the control group but no significant difference between the groups. Change was in the positive direction on all outcomes but one PedQL in the control group showed a negative change. The changes at three months were larger than

those at nine months (table 9) for the two parenting wellbeing measures but not for the child outcome.

Table 6: 3 month outcomes: Summary of parameter estimates for mixed effects models using ITT analysis

Outcome/parameter	Estimate	Std Error	p-value	95% Confidence interval
Parenting stress index				
Control	0.9907	1.6506	0.549	(-2.2633, 4.2448)
FLNP	3.9903	1.6902	0.019	(0.6582, 7.3224)
Difference	2.9996	2.3625	0.206	(-1.6579, 7.6570)
PedQL				
Control	-0.4757	0.7738	0.539	(-2.0003, 1.0488)
FLNP	0.2111	0.8269	0.799	(-1.4182, 1.8403)
Difference	0.6868	1.1325	0.545	(-1.5445, 2.9182)
WEMWBS score				
Control	0.8516	0.7758	0.273	(-0.6768, 2.3799)
FLNP	2.2562	0.9947	0.031	(0.2227, 4.2897)
Difference	1.4046	1.2615	0.270	(-1.1182, 3.9274)

Table 7 shows the three month results when analysis is conducted taking the number of FLNP sessions attended to be continuous. The pattern is similar to that in table 4. Positive change is observed for attending a FLNP session for two (PedQl and WEMMBS) out of the three variables. Comparing results in table 4 , the improvement at month 9 for parents who did not attend a FLNP session is greater than improvement at month 3 for the same parents. Also, except for PedQL, an extra session of FLNP leads to more improvement at month 9 than at three months, suggesting sustained change in parent wellbeing.

Table 7: 3 month outcomes: Summary of parameter estimates for mixed effects models using taking the number of sessions of FLNP attended as continuous

Outcome/parameter	Estimate	Std Error	p-value	95% Confidence interval
Parenting stress index				
Intercept	3.0961	1.4604	0.035	(-0.2172, 5.9751)
Session	-0.2262	0.3017	0.454	(-0.8210, 0.3685)
PedQL				
Intercept	-0.5588	0.6913	0.421	(-1.9207, 0.8032)
Session	0.1455	0.1440	0.313	(-0.1382, 0.4292)
WEMWBS score				
Intercept	1.2193	0.7034	0.085	(-0.1674, 2.6061)
Session	0.0663	0.1512	0.661	(-0.2318, 0.3644)

Table 8 shows the results after categorising the families into the same three categories. Except for PedQL categories "No FLNP session" and "1–4 FLNP sessions", there was improvement in scores from baseline to month 3 even for parents who did not attend a FLNP. These results are somewhat different from those in table 5 because, except for the PedQL, the difference in change scores attributable to 5-10 sessions is not greater than the difference attributable to 1-4 sessions. However, none of these differences are statistically significant.

Comparing results in Table 8 to those in table 5, differences between groups in parent wellbeing scores (PSI and WEMWBS) increased over time with more improvement in parents attending 5-10 sessions and less in those attending 1-4 sessions.

Table 8: 3 month outcomes. Summary of parameter estimates for mixed effects models when number of FLNP sessions attended is categorised into 3 categories

Outcome/parameter	Estimate	Std Error	p-value	95% Confidence interval
Parenting stress index				
No FLNP session	2.2720	1.5411	0.142	(-0.7661, 5.3101)
1 – 4 FLNP sessions	5.3478	3.5926	0.138	(-1.7348, 12.4305)
5–10 FLNP sessions	1.7619	2.1707	0.418	(-2.5176, 6.0414)
Difference (1-4)	3.0758	3.9092	0.432	(-4.6309, 10.7826)
Difference (5-10)	-0.5101	2.6621	0.848	(-5.7583, 4.7381)
PedQL				
No FLNP session	-0.5260	0.7261	0.470	(-1.9566, 0.9047)
1 – 4 FLNP sessions	-0.9167	1.7740	0.606	(-4.4117, 2.5784)
5–10 FLNP sessions	0.8738	1.0432	0.403	(-1.1817, 2.9292)
Difference (1-4)	-0.3907	1.9168	0.839	(-4.1672, 3.3859)
Difference (5-10)	1.3998	1.2711	0.272	(-1.1046, 3.9041)
WEMWBS score				
No FLNP session	1.0118	0.7311	0.168	(-0.4289, 2.4526)
1 – 4 FLNP sessions	3.4502	1.7232	0.046	(0.0550, 6.8454)
5–10 FLNP sessions	1.5034	1.1639	0.199	(-0.8019, 3.8087)
Difference (1-4)	2.4384	1.8364	0.185	(-1.1790, 6.0557)
Difference (5-10)	0.4915	1.3242	0.711	(-2.1187, 3.1018)

Economic evaluation results

o *Implementation costs*

Table 9: Summary of costs associated with implementation

Total costs	Cardiff	Torfaen	Newport	Caerphilly	TOTAL
Salaries	£63,002.00	£33,341.40	£52,772.00	£44,423.00	£193,538.00
Training	£5,801.90	£4,733.90	£5,081.90	£5,144.00	£20,761.70
Room hire	£3,883.89	£3,003.00	£3,000	£3000.00	£12,886.89
Course materials	£3,750.00	£1,625.00	£2,250.00	£2,250.00	£9,875.00
Crèche	£17,862.66	£17,097.96	£15,000.00	£15,000.00	£6,4960.62
Total cost	£ 94,300.45	£59,801.26	£78,103.90	£69,827.00	£302,022.21
No of courses	15	13	15	15	58
Cost per 11 week programme	£6,286.70	£4,600.00	£5206.93	£4,654.47	£5,207.28
Mean cost per 11 week programme					£5,187.03 (SD=782.71)
Mean cost per family per programme (based on 8 parents attending)					£648.38(SD=97.84)
Mean cost per family per programme (based on 13 parents invited to attend)					£399.00
Mean cost per family per programme (based on 6 parents completing the programme)					£864.51

Table 9 presented the costs of the programme to Flying Start. The main variation in costs was due to the different staff resources used to deliver the FLNP at each of the sites. Costs are presented based on a best estimate of a) mean number of parents per programme invited to attend (13) ; b) mean number of parents attending the programme at the start (8) and c) mean number of parents fully completing the programme. The mean cost per family per programme (based on 8 families attending)

was £648.38. This was the cost used in the complete case analysis. The impact of other costs on cost utility were evaluated in sensitivity analyses.

- ***Parental Resource utilization costs***

Results for resource utilisation and parent costs are summarised in Tables 10 and 11. Average overall time expenditure for parents in the intervention group (n = 99) was 16.8 hours per parent (Table 10), which equates to expenditure per parent of £149.50 (Table 11). Travel costs were low (£5.59) as were other costs (£1.13) giving an average participation cost of £156.22.

One parent in the intervention group took part in an additional programme (a WEA Child Development course) of 8 sessions, each of 2 hour duration. Thirteen parents in the control group (n = 143) attended support programmes (e.g. Parent Plus, Freedom Programme, Young Mums, Homestart, Early Years and other parenting programmes). Due to the small number of parents attending sessions in the control group and because of the general lack of travel data available, the mean time expenditure and cost for each parent of the control group is relatively low at 1.1 hours and £8.90, respectively.

Table 10: Summary of parent resource utilization

Resource	**Overall use (all parents)**	**Mean use per parent**	**Standard deviation**
FLNP sessions • Control • FLNP	 n/a 735.000 sessions	 n/a 7.424 sessions	 n/a 2.767 sessions
Other sessions • Control • FLNP	 100.000 sessions 8.000 sessions	 0.709 sessions Only one parent attended	 2.451 sessions n/a

Resource	Overall use (all parents)	Mean use per parent	Standard deviation
Travel – Walk • Control • FLNP	 No data available 110.700 hours	 - 1.118 hours	 - 1.186 hours
Travel – Public • Control • FLNP	 No data available 13.000 hours	 - 0.131 hours	 - 0.520 hours
Travel – Taxi • Control • FLNP	 No data available 5.440 hours	 - 0.055 hours	 - 0.251 hours
Travel – Own car • Control • FLNP	 No data available 46.070 hours	 - 0.465 hours	 - 0.660 hours
Travel – Lift • Control • FLNP	 No data available 3.910 hours	 - 0.039 hours	 - 0.175 hours
Parent time overall • Control • FLNP	 153.750 hours 1665.120 hours	 1.090 hours 16.819 hours	 4.062 hours 6.617 hours

Table 11: Summary of parent cost

Resource	Mean cost (£)	Std. error	95 % CI
Participation time • Control • FLNP	 8.91 149.50	 2.803 6.801	 (3.369, 14.454) (136.007, 163.003)
Travel • Control • FLNP	 0.02 5.59	 0.0178 1.073	 (-0.017, 0.053) (3.456, 7.714)
Other (unspecified) • Control • FLNP	 No data available 1.13	 - 0.804	 - (-0.464, 2.727)
Overall parent cost: • Control • FLNP	 8.93 156.22	 2.809 7.087	 (3.376, 14.483) (142.158, 170.286)

- ***Cost Consequences Analysis***

These are the relatively modest costs required to achieve the modest outcomes presented in the previous section, none of which showed statistically significant differences between control and intervention groups.

- ***Cost Utility Analyses***

Table 12 summarises the average costs of the programme from the public purse and from public purse combined with parental costs. It shows the difference in QALY gain experienced by parents in the FLNP compared to control – a non-significant difference.

Table 12: Cost utility of FLNP at 9 month follow up

	FLNP	**N**	**Control**	**N**	**Difference (95% CL)**	**P value**
Cost per programme	648.38				648.38	
Overall cost	804.60		8.93		795.67	
QALYs (difference from baseline) over 9 months	0.055	144	0.047	143	-0.968-0.111	0.89
Cost per QALY (5 years) gained compared to control from public sector perspective	£21,600		n/a			
Cost per QALY (10 years) gained compared to control from public sector perspective	£12,960		n/a			
FLNP Implementation cost / family(Cardiff) £	785.83		n/a			
FLNP Implementation cost / family(Newport) £	650.87		n/a			
FLNP Implementation cost per family(Caerphilly) £	581.81		n/a			
FLNP Implementation cost per family(Torfaen) £	575.01		n/a			
Parents out-of-pocket expenses (travel) £	5.59	99	0.18	141	5.58 (3.80; 7.34)	**< 0.001**
Parents time expenditure in hours	16.82	99	1.09	141	15.73 (14.37; 17.09)	**< 0.001**

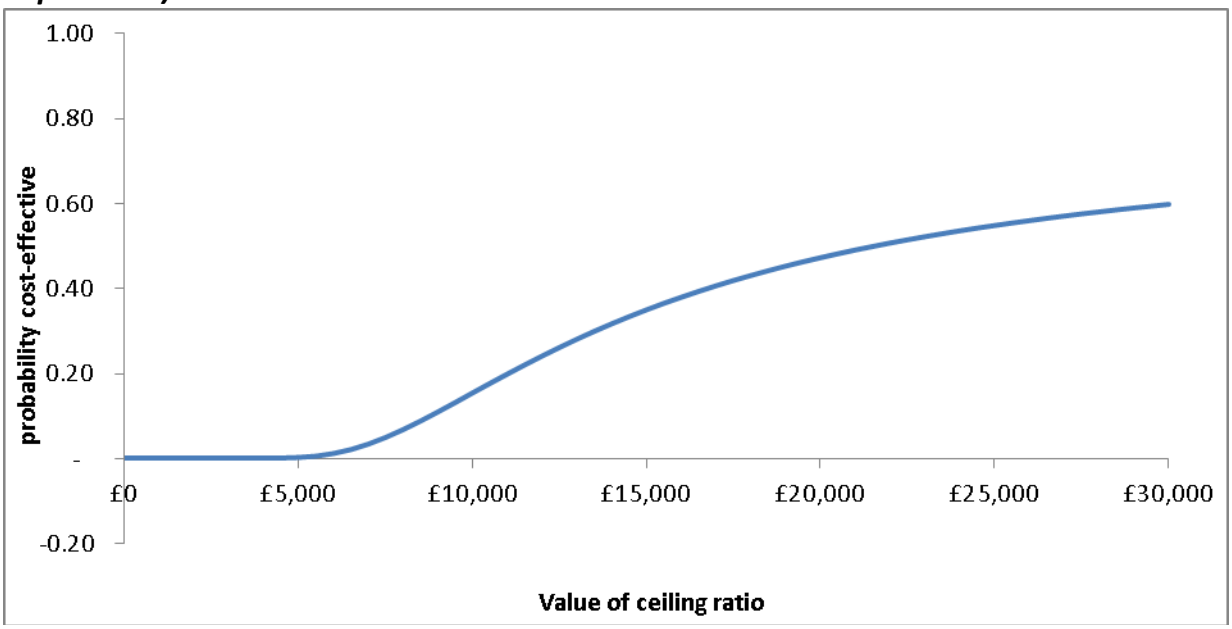
Complete Case Analysis

Table 12 also shows the Cost per QALY of the programme. Using the 5 year time horizon and basing analyses on all cases with complete data, the incremental cost per QALY gained was £21,600 which is just outside the £20,000 threshold regarded by NICE as representative value for money. The probability that the cost per QALY of FLNP would be less than £20,000 is 45%. The probability that it would be less than the upper limit used by NICE of £30,000 is 60%. Using the 10 year time horizon, the incremental cost per QALY gained is £12,960 which is well within the £20,000 NICE threshold as representing value for money with a probability of 60%. Adjusting the programme costs to the implementation cost of the cheapest centre (Torfaen) would reduce the 5 year incremental cost per QALY to £ 19,167 with a 50 % chance of being below £ 20,000, while increasing implementation cost to the level of the most expensive centre (Cardiff) gives an incremental cost per QALY of £ 26,194 with a probability of 37 % of the programme being below the NICE threshold. Using the average cost per family that was invited to take part in the sessions the incremental cost per QALY is £ 13,300 (probability of being below £ 20,000 60 %), whereas the incremental cost per QALY would be £ 28, 817 (probability of cost-effectiveness as regarded by NICE 32 %) if the average number of parents who completed the programme were to be used for calculations. Including parent costs into the analysis changes the incremental cost per QALY to £26,536 and the probability of the cost being below £ 20,000 to 36 %.

Mean imputation

All analyses were repeated using mean imputation to enable inclusion of cases with incomplete data. The results were the same as for the complete case analysis.

Figure 6: that FLNP is cost-effective using 5-year time horizon (mean imputation)



- ***Programme fidelity***

Table 13 shows the distribution of fidelity scores for each programme against on 9 individual components. Each programme received a score from 1 to 4, with 4 being the maximum score.

Table 13: Overall Fidelity Score Distributions

Fidelity Ranking 1 low, 4 high)	**% of programme scoring at each fidelity rank**			
	1	**2**	**3**	**4**
Welcome	2	14	38	46
Family Feedback	4	17	44	35
Topics before break	6	21	40	33
Topics after break	5	26	43	26
Time to have a go	0	22	22	56
Modeling group rules	4	25	38	33
Active listening	0	40	43	17
Empathy	4	25	33	38
Nurturing Environment	4	18	31	47

Figure 7 Mean Fidelity Scores by Programme Component

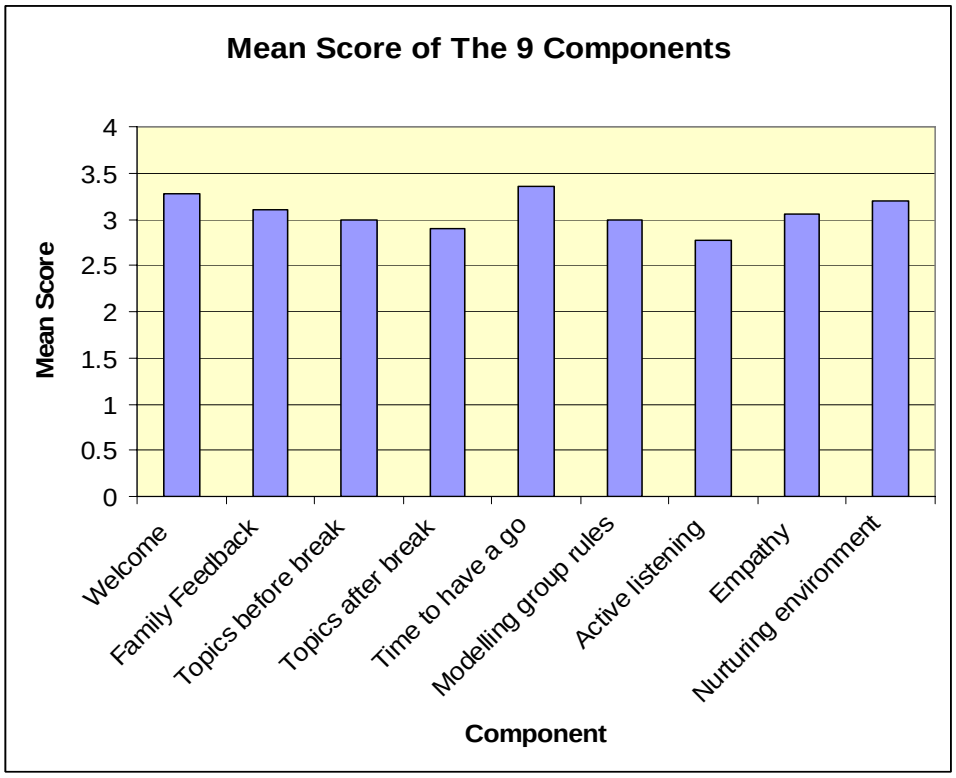


Figure 7 shows the mean scores for each component of the programme

The overall fidelity score for courses in Cardiff was 87%, Newport 82%, Torfaen 72% and Caerphilly 60%. Fidelity in phase 1 courses was 85%, phase 2 - 83%, phase 3 - 75%, phase 4 - 77% and phase 5 - 47%. Fidelity was much lower in phase 5 due in part to the higher number of families from Caerphilly in this phase of the trial.Fidelity for the individual weeks of the course is given in table 14.

Table 14. Mean percentage fidelity score by week of FLNP course

Week of FLNP course	2	3	4	5	6	7	8	9	10
Mean percentage fidelity score	88	82	76	72	82	70	70	63	75

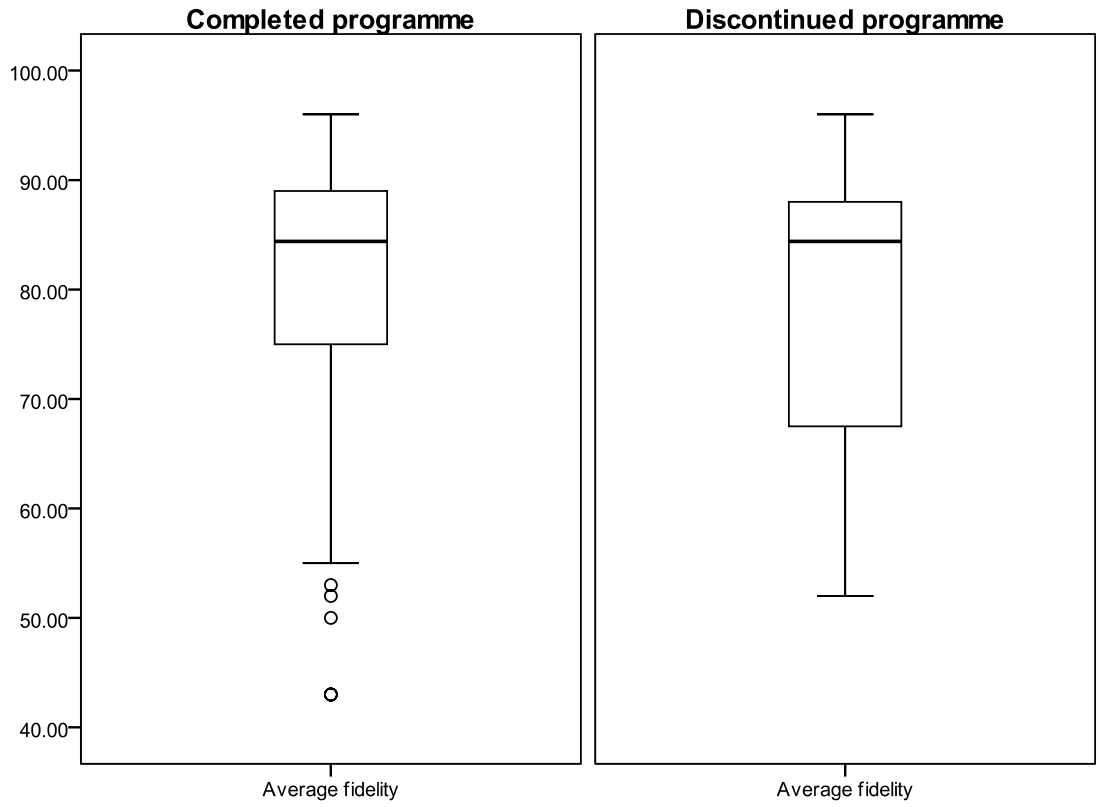
Analysis of the impact of different levels of programme fidelity on outcomes

Fidelity, attendance and drop out.

We fitted a logistic regression model to assess whether the fidelity score of the programme attended predicted whether a parent discontinued the FLNP programme. When the fidelity increased by 1%, the odds ratio of discontinuing FLNP programme was 0.992 (p-value=0.604). This means when the fidelity increased by 1%, the odds of discontinuing the programme decreased by 0.8 % (100 *x* [1-0.992]). Higher fidelity was associated with higher retention.

Figure 8 shows boxplots of programme fidelity among families who completed the programme (no. of children is 77) and those who discontinued the programme (number of children is 40). There does not appear to be a difference between the two groups but the spread of programme fidelity is greater amongst parents who discontinued to the programme.

Figure 8: Boxplots for average fidelity against FLNP programme



Effect of programme fidelity on outcomes

To assess the effect of programme fidelity on outcomes, we used the average fidelity for the programme attended, adjusted for the number of sessions that parent attended. We fitted a model with a fidelity-session interaction but the interaction term was not significant and so we dropped it in the model. The results of the fitted multi-level models are given in table 15. The estimate for fidelity gives the increase (or decrease) in parenting improvement when fidelity increases by 1% after adjusting for the number of sessions attended. The estimate for session gives the increase in parenting

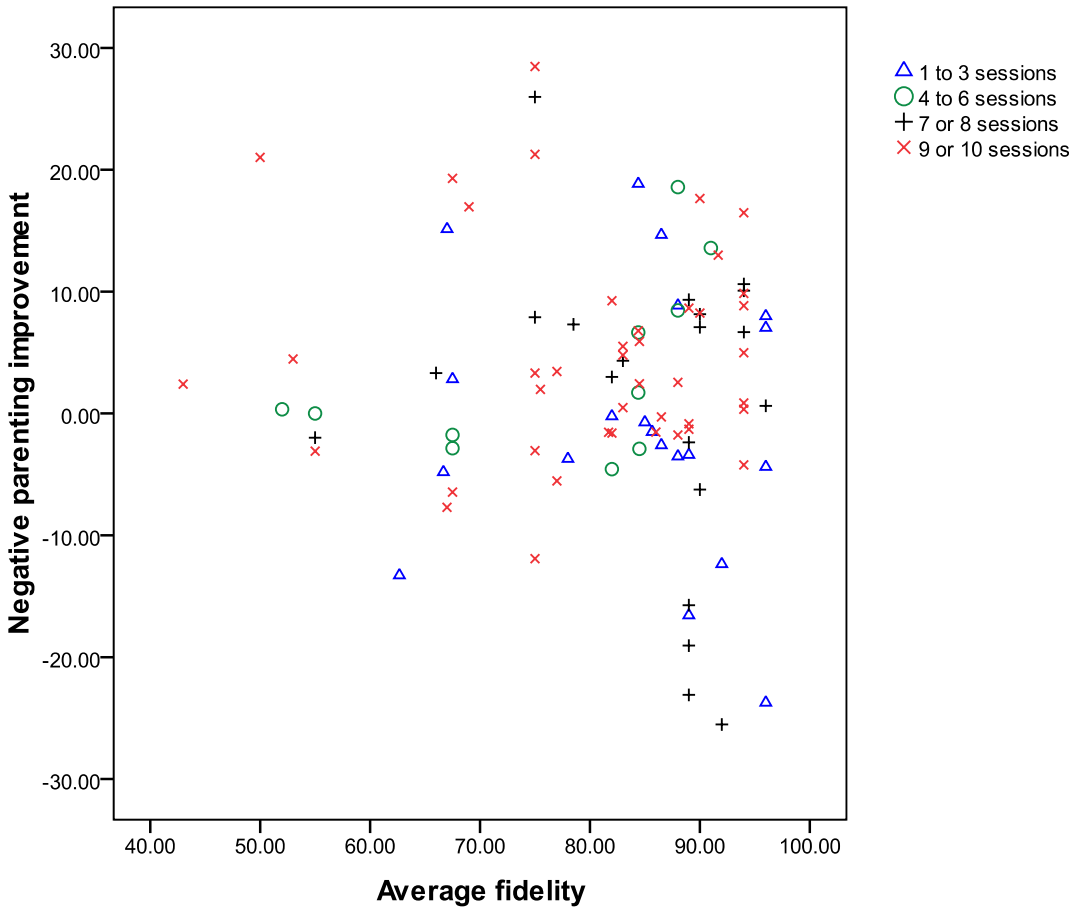
improvement when a parent attends an extra session after adjusting for the average fidelity score. For negative parenting, after adjusting for the number of sessions, an increase in fidelity of 1% was associated with a non-significant deterioration after 9 months (- 0.0612). In contrast after adjusting for the average fidelity, parenting improved by an average of 0.5005 for each session attended, also a non-significant difference. Increases in both fidelity and session attendance were associated with non-significant improvements in parenting as measured by supportive parenting.

Table 15 Negative and supportive parenting against fidelity

Outcome (n=93)	Estimate	Std Error	p-value	95 % CI
Negative parenting				
Fidelity	-0.0612	0.0910	0.503	(-0.2421, 0.1197)
Session	0.5005	0.3496	0.156	(-0.1945, 1.1955)
Supportive parenting				
Fidelity	0.0234	0.0251	0.355	(-0.0266, 0.0733)
Session	0.0577	0.0965	0.551	(-0.1342, 0.2497)

Figure 9 shows a scatter plot of average fidelity against changes in negative parenting. Changes in negative parenting did not depend on the fidelity quality of the courses. For example, it seems for parents who attended 7 or 8 sessions, improvement in negative parenting is lower for parents who attended sessions with higher fidelity and for parents who attended between 4 and 6 sessions, improvement is higher for parents who attended sessions with higher fidelity. This anomalous result may explain the negative estimate obtained in the multi-level model for negative parenting.

Figure 9: a scatter plot of average fidelity against negative parenting



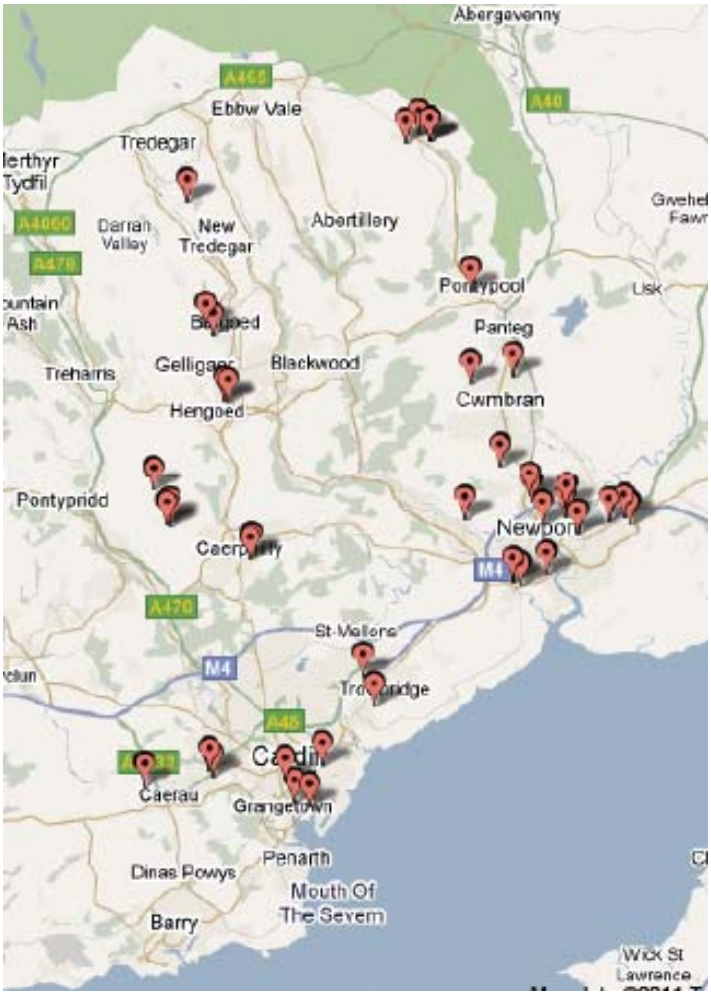
Qualitative Interviews

23 interviews were carried out with people who attended the course and took part in the research and 11 interviews with people who refused to take part in the research but attended the course. 9 Interviews were conducted with people who refused both the course & research.

- ***Demographic Information***

All but two of the 41 interviewees were biological mothers with one foster mother and one grandmother. 80% were white British. The other 20% includes six other ethnic groups. Half the sample owned their own homes and half rented. Just under half of the mothers were employed. Half were between the ages of 25-34, 3 younger mothers and 18 older. Families homes are marked on the map below.

Figure 10 Home address of interviewed parents



o ***Findings***

Reasons for wanting to go on the FLNP and for taking part or refusing the trial

Parents reported three main reasons for wanting to take part in the FLNP: -

- they wanted to address problem behaviour in their children -

"I was having problems with my little boy, he was biting and not listening to me and just being really naughty to be honest"

- they wanted to improve their parenting skills:-

- *"If there's anything out there that can help me do a better job then I'm up for that"*

- they wanted to do the course because their friends or peers were doing it:-

"My mate was doing it so I thought I'd give it a go"

They reported two main reasons for wanting to take part in the research/ trial :-

- they were asked to do so by a practitioner

– *"I did it because I was asked"*

- they knew the course was under threat and wanted the research to go ahead so the course would remain available to other parents in the future:-

'*Because I just thought, you know that kind of programme, especially round this area where there are quite a few problems with children, it's quite handy. It'll be a shame to withdraw a programme when it is needed in the area. So that's obviously why.*

'There were two common reasons parents declined to take part in the research:-

- they didn't want to participate in the video of parent child interaction at a meal time - "filming my kids and all that, watching what I do"

- they felt the trial would be too time consuming

- "*And as for the research maybe just make it a bit quicker rather than, you know. When you've got children that's a long time"*

Some parents echoed the reasons given for not wanting to take part in the trial, collected in the wider study of reasons for refusal shown in the Consort diagram. They wanted to go on the course now and did not want to wait for the waiting list course because they were desperate

'I was just desperate to go on the course…. ..' It could have been six months to a year or something before I could have gone on it' (the waiting list control condition).

We undertook an analysis of reasons for wanting to do the FLNP in parents who also consented to take part in the trial and in parents who refused to take part in the trial but did attend the FLNP.

Table 16: Did FLNP and participated in the trial (n=15)

Reason	**Number**
Doing the course because friend was doing it or someone else wanted them to	5
Interested in everything new; everyone should do it	5
General - meet others, get confidence	3
Want help and advice with parenting; having problem with child	2

Table 17: Did FLNP refused research (N=10)

Reason	**Number**
Really needed the programme now because having problems with child's behaviour	4
Knew it would be good for me/my child	4
Doing course because others going or someone else put name down	2

There is some indication from these data that parents who agreed to take part in the trial were motivated more by altruism and less by need for support with their parenting than were the parents who refused to take part in the trial. This raises questions about the extent of 'readiness for change' in parenting amongst those who agreed to take part in the trial and whether the trial might have been subject to recruitment bias in this respect. In the real world setting where there was no pressure to take part in a research study with the time commitment and risk of allocation to control arm, FLNP courses might be expected to attract a group of parents who were more 'ready to change'.

Strengths and weaknesses or the course

Most parents said they really enjoyed the course and appreciated the facilitators–

"*It was all very bright and cheerful and happy and fun, it was fun*"

"As soon as you walked in the room, they just made you feel welcome, from the minute you walked in, to the minute you left, it was just --, it was just nice"

"They were just really nice, they were friendly, open, you know, if you wanted any advice, they were just really nice women"

They particularly enjoyed sharing ideas

- "*We discussed many things that most of us had the same problems but each one has his ideas, but when we shared them, we could solve the problem. So we shared our ideas and it was really good*"

And found the materials easy to understand

- "*Everything was pretty simple, and understanding*"

A few parents commented on negative aspects relating to other people on the programme

- "*I would have probably opened up a bit more if it wasn't other people there that I knew*"

- "*It would have been nicer to share experiences with a bigger group*"

Most respondents found it difficult to come up with any weaknesses relating to the

course or facilitation, but two commented as follows:

"We didn't get our books straightaway…because she kept forgetting them"

"I didn't like the fact they were--, the way that they had this opinion of men when actually all men aren't the same"

Perceived impact of the course

Parents commented on particular skills they had learnt and applied successfully

including practical things like sticker charts:

– "*It's cheap, its easy and they just love it*"

as well as emotional literacy

"*Makes you more…empathic. I can relate sometimes just by listening but before I was thinking, "why's he telling me this? What's he getting upset about?" but now I understand so its helped a lot*"

"*You respect people more and take in their, like, views, and stuff now*"

"*Whereas before you might blow up and start screaming, and you sort of stand back a minute, think about it, and then go in to it a different way*"

and the need to look after themselves well to be good parents:-

"*I learned things like self nurturing, cause when we, you know, you just think parenting is all about your child and just forget about yourself, but you have to nurture yourself, even if it's just doing your nails [laughs] you're forgetting about being a parent for one minute*"

They also reported improvement in aspects of their personal wellbeing including self confidence and interpersonal relationships:-

"*I've started work since doing--, since the course, because I feel a bit more confident to speak in front of people, so that was nice. So, yeah, really pleased about all that*"

- "*It did work, better on, because my partner no longer talks to me like something else [laughs], and the kids aren't talking to me 'cause they'd heard him, so he's not speaking to me like it and it's gone a lot better, yeah*"

- "*I've met some really good friends from parent nurturing and I see them all the time*"

Some parents couldn't get some of the ideas of the course to work for them

'Time out – "'Keep trying, it will work' – but we kept trying and it just didn't work"

The key restraints about implementing what parents had learnt on the course were lack of support from partner and time constraints due to doing a paid job,

- "*My problem was, that I wouldn't be able to commit to every week…we have no babysitters, we have no one around to help"*

- *"Apart from his dad not taking part in it and not listening, that was the really hard thing. So really I never followed through with it because you can't tell a child two things as It's just going to confuse them, isn't it?"*

Chapter 4 : Discussion and interpretation of findings

This trial aimed to establish the effectiveness of an existing parenting programme in a deprived area in which the programme was already available on a universal basis, against a backdrop of general support for parenting in FSPs. To our knowledge there have been no other attempts to trial parenting programmes in such settings. RCTs on the impact of the Incredible Years and Triple P programmes for example have been undertaken in targeted or indicated populations or using area-based approaches involving both universal and targeted approaches.

Challenges

Many challenges were confronted during implementation of the trial, ranging from severe snow falls in the Valleys preventing recruitment and attendance in January and February programmes, to delays in research governance approvals resulting from NHS reorganisation and swine flu, and reluctance to recruit on the part of FSP practitioners, some of whom, in spite of information on the rationale for undertaking the trial, opportunities to discuss it and information on how to recruit, remained unconvinced of the value [57]. However, although recruitment needed to be extended both geographically and temporally, the full sample size was recruited and follow up rates were exemplary. Within the constraints of the setting and intervention the implementation of the trial was as robust as it could have been.

The most important challenges were the well recognised threats to health/wellbeing promotion and disease prevention trials – those of poor exposure amongst the intervention group, contamination of the control group and loss of fidelity of implementation of the programme in some areas. Less than half the families attended the FLNP and therefore only half could have derived any benefit. Our predicted programme non-attendance and dropout rate, based on provision of this programme in other settings, was 16%. In the event the rate was 52.3%. Non-attendance is an issue in all parenting programmes and methods and approaches have been developed to increase retention. The FLNP includes these methods and approaches and in other settings has good retention rates. At the same time 10% of the control group violated the rules of the trial and attended a FLNP course before the nine month follow up. A further 9 % of these parents accessed different parenting support courses available in the locality. Approaching 20% of control families were thus exposed to parenting support. Only one of the intervention group families accessed any other type of parenting support. The main trial results therefore compare the changes in parenting and family wellbeing among a group in which roughly one in two parents were exposed to the FLNP with changes among a control group in which roughly one in five parents attended the FLNP or other parenting support programme.

With regard to programme fidelity, programmes in two of the areas were run with exemplary fidelity, those in a third area were intermediate and those in the fourth did not meet the, albeit very high, standards for running FLNP in all respects. The latter was the last area to be recruited. These data raise the question as to whether pressure to

recruit within the time frame of the FSP budget and the consequent need to extend the trial to a fourth county, thereby extending the budget, may have also compromised the outcomes. The parents going through some of the trial programmes would not have been expected to benefit as much as those in the other two high fidelity areas. Statistical examination of the impact of programme fidelity failed to provide significant findings. A non-significant association between fidelity and attendance hints at the possibility that discontinuation of the programme may have been more likely in the lower fidelity programmes, but we were unable to demonstrate a relationship between programme fidelity and trial outcomes. It is, however, important to note that the programmes with the highest level of fidelity were those with the highest costs and those with the lowest the cheapest to run.

This was a pragmatic trial looking at provision as it is on the ground. It contrasts with trials carried out in carefully controlled conditions undertaken with families who have come forward because they or someone else had concerns about their children's behaviour.

Outcome analyses

The results of the 'treatment allocated' analyses – the most robust of statistical tests in which change among all families allocated to FLNP was compared with change among all families allocated to control regardless of exposure - showed no statistical difference between intervention and control groups on any of the outcome measures. This means that the differences we did observe could have arisen by chance.

Against a backdrop of improvement across the board in both groups, families in the FLNP arm of the trial improved more than those in the control arm on 12 out of 18 outcomes. The differences observed, however, were very much smaller than those on which the sample size was based and the latter was constrained by the funding available. To be powered to detect a difference of the size we observed in negative parenting we would have needed a sample size of around fifteen times that in the trial which we undertook. Such a trial would be very expensive to run, exceeding the budgetary ceilings available to the local authorities and the WAG when this trial was set up. Given the relatively small impact and low cost of the intervention it might be considered that the opportunity costs of such a trial were too high.

Although not in any way a measure of the effectiveness, the overall improvement on many outcome measures in both FLNP and control groups could suggest that the FSP is making a difference to parenting and wellbeing among families living in the area. Wellbeing promotion is recognised to be more effective with multi-modal approaches of the sort that FSP provides. Such settings, however, present particular challenges for research which is endeavoring to establish an evidence base for just one of the potentially contributing programmes.

Because we encountered problems with exposure to the intervention in the FLNP group and contamination in the control arm, it was appropriate to undertake an analysis of effects according to level of exposure to the programme. This compares outcomes in all

families who attended the programme regardless of their allocated group, to outcomes in all families who did not attend the FLNP. Whilst intuitively a better approach in this situation, such analyses loose the benefit of randomisation and it therefore cannot be assumed that the families who attended were the same in all other respects as families who did not. Positive results could arise because parents who attended more sessions were very different from those who dropped out and not because of the impact of the programme.

In these 'treatment received' analyses, the relative improvements amongst parents who attended more than 5 sessions were larger than the relative improvements amongst all parents allocated to FLNP in the trial and for one outcome, in one analysis, the hyperactivity scale of the PrePACs, achieved statistical significance. As we have undertaken many analyses and the p value of 0.05 represents a chance of 1 in 20, it is probable that this finding has arisen by chance. However it is notable that in these analyses all but three outcomes – the two internalising scales of the PrePACs scale and one of the mealtime video scales – rate of positive interactions (involvement) – favoured the FLNP group. PrePACs is a clinically validated measure of conduct disorder, hyperactivity and internalising behavior problems which has been used successfully in trials of indicated and targeted parenting programmes. Whilst it is important not to over interpret these findings, they are compatible with the goals of the FLNP and with qualitative results which indicate that parents became more sensitive to their children's emotional needs. So whilst the FLNP was providing parents with the skills and resources to reduce internalising problems, it might also have given them the ability to recognise

problems they had not noticed before. These two effects might work differently in universal level and targeted and indicated programmes, resulting in increased reporting of problems after universal delivery.

In these analyses the lower level of improvement amongst parents who attended 1-4 sessions suggests that there may be differential effects in outcome by number of sessions attended. The result could also indicate that the parents who were not benefiting were those who dropped out of the course early.

Findings of the economic analyses

The aim of the economic evaluation was to measure the cost consequences and cost utility of the FLNP compared to no intervention from a public sector, parent and societal perspective. In this trial both the costs and the utility of the programme were small, but the key issue was that measurement of programme utility (QALY) could only be undertaken on the basis of change in parental wellbeing. There are as yet no suitable scales which could have been used to measure QALY's in children, so the estimate of QALY gained is based entirely on changes in parental wellbeing. As parenting programmes have valuable effects of on children's current and future wellbeing, this is an important weakness in the estimate, which would tend to under estimate the true cost utility. The five and ten year estimates are also based on the assumption that changes observed in parental wellbeing at nine months after the beginning of the trial continued for first five and then for ten years. Differences between the FLNP and

control group in terms of parental wellbeing were more marked at three month follow up than at nine months. Whilst it is likely that changes maintained at nine months (six months after the programme had finished) represent a permanent change, it is also possible that these wellbeing scores continued the decline observed between three and nine month after the nine months follow up. In this case the cost per QALY would be underestimated. On the other hand in the light of reviews suggesting there are lasting effects of parenting interventions, the assumption is reasonable.

Based on both complete case analyses and mean imputation and the above assumptions the incremental cost per QALY of the FLNP was estimated as £21,600 at 5 years. This is only just outside the £20,000 lower threshold regarded by NICE as representing value for money, and within the higher bracket of £30,000. At 10 years, the incremental cost per QALY gained was £12,960 which is well within the £20,000 NICE threshold. Probabilistic analyses suggest that these figures have between a 45% and 60% chance of being true. These results suggest that in spite of the lack of statistically significant findings, the low cost of the FLNP means that it could still represent an efficient use of public sector funds.

The costs of FLNP appear to be relatively modest against other parenting programmes [59]; and might be reduced further through achieving cost reductions in programme provision, given the difference in costs across provider areas. However it may also be that reductions in costs can only be achieved at the expense of programme fidelity. Parental costs were significantly different between FLNP and control group; largely

down to the costs associated with parental participation time, but it was not possible to ascertain whether these were offset by differences in resource utilisation of other services or whether this group of parents made little use of other services. Incorporating parental costs increase the cost per QALY gain above £20,000 NICE threshold in all scenarios.

Despite the careful administration of a self-reported questionnaire, the quality of information provided by participants was limited with no meaningful data obtained on the contacts with other services during the follow-up period. Careful checks have been undertaken with regard to missing data but the findings indicate that parents did not (or choose not to report contacts with other services). Therefore we have been constrained on the ability of our study to report the findings from a 'mixed public sector' perspective and based on the quality of data obtained and short follow up period, our study has not been able to address whether FLNP can achieve long-term benefits i.e. on health, social, educational and criminal justice outcomes. These limitations have been recognised in other studies [60]. A recent study has attempted to estimate the cost-effectiveness of the Incredible Years Programme in a targeted population on key outcomes in later life [61]. This study demonstrated favourable long-run economic returns. Further work is warranted to examine FLNP in this context with the potential in using baseline findings to develop a model to assess longer–term effects so as to inform decision-makers as to the relative efficiency of parenting programmes.

Qualitative findings

There is some evidence from the qualitative data that parents accepting recruitment were more likely to be motivated by altruism than those who did not, in particular, by wanting the research to happen so that the programme could be retained in the localities for other parents [58]. It is not unreasonable to suggest that these parents might have had less room for improvement in their parenting than other parents. Other common reasons for taking part were doing so because a friend was doing it, to make friends or to learn something new. There were also clearly parents in the trial who wanted help with their parenting, but this group was, relatively speaking, smaller than it was in the group who refused to take part. Consenting to randomisation requires an element of equipoise or indifference on behalf of participants as well as trialists and practitioners, and this position is very different from the position of readiness to change which is the optimum stage for benefiting from health promotion or social change programmes like FLNP.

The qualitative data relating to the perceived impact of the programme on families tell the same story as previous qualitative studies of this programme [40]. They show that in this small sample of trial families, many parents absorbed the messages of the programme and went home to put them into action, improving their own and family wellbeing in the process. Whilst some parents reported not being able to benefit from some of the advice, these were in the minority in the qualitative sample. Very few parents voiced criticisms of the programme in spite of encouragement to do so.

Qualitative findings cannot provide data on the proportion of families who changed nor give quantitative estimates of the extent of change, their purpose is to identify potential issues and findings that were not captured by the primary outcomes. However, although they do not prove, they suggest that recruitment bias may have been operating in this trial to the detriment of programme effectiveness and they also show that from the perspective of most of the families interviewed the programme 'worked' at least to some degree.

Other results

The three month results suggest that differences in parental wellbeing were greatest at the end of the programme and decline over the next six months . In contrast differences in child wellbeing as measured by the PedQL increased over time. The lack of statistical significance of all of these findings suggest the need for cautious interpretation. Programme fidelity was associated with higher programme costs. Although there was some suggestion that higher fidelity was associated with better retention it was not possible to show an effect of fidelity on outcomes.

Chapter 5: Conclusions

The results of this trial fail to show that FLNP improved parenting or wellbeing more than could be expected by chance. Due to the low cost of the programme, the modest improvements which were observed are, however, compatible with cost utility as determined by NICE – the National Institute for Health and Clinical Excellence. Calculations of QALYs (quality adjusted life years) on which the cost utility estimates are based so far take no account of the modest benefits to child wellbeing. Were a way to be found to include these in the QALY calculations, the cost effectiveness would increase. The underlying improvement in parenting scores in the control arm of the trial provides some support for the belief that the Flying Start Programme (FSP) is improving parenting and family wellbeing amongst families living in deprived areas. At the same time the FSP setting presented challenges for this RCT including contamination of the control group due to the ready availability of parenting support. Contamination combined with low levels of attendance, reduced the study's power to detect any impact of the FLNP and together these factors are likely to mean that we have underestimated the effectiveness of the FLNP.

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