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Evaluation of an online parenting programme based on 'The Little parent Handbook': Study protocol for a pilot randomised controlled trial

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Title: Evaluation of an online parenting programme based on 'The Little Parent Handbook': Study protocol for a pilot randomised controlled trial

Authors: Dawn Adele Owen, Nia Griffith, Judy Hutchings

Author details:

Centre for Evidence Based Early Intervention, School of Psychology, Nantlle Building, Normal Site, Bangor University, Bangor, Gwynedd, LL57 2PZ, UK (01248 383 758).

Email: dawn.a.owen@bangor.ac.uk

School of Psychology, Wheldon Building, Room 113, Bangor University, Bangor, Gwynedd, LL57 2PZ, UK.

Email: n.griffith@bangor.ac.uk

Centre for Evidence Based Early Intervention, School of Psychology, Nantlle Building, Normal Site, Bangor University, Bangor, Gwynedd, LL57 2PZ, UK.

Email: j.hutchings@bangor.ac.uk

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Abstract

Introduction: The online parenting programme based on 'The Little Parent Handbook' is a web-based parenting intervention for parents of children aged 3-8 years who would like to learn more about positive parenting. The programme focuses on strengthening parent-child relationships through encouraging positive child behaviour. This trial will evaluate whether the intervention is effective in increasing the use of positive parenting strategies outlined in the programme using both parent report and blind observation.

Methods and analysis: This is a pilot randomised controlled trial with intervention and wait-list control conditions. The intervention is a ten-week online parenting programme to promote positive parent-child relations by teaching core social learning theory principles that encourage positive child behaviour, primarily through the use of praise and rewards. Health visitors and school nurses will circulate a recruitment poster to parents of children aged 3-8 years on their current caseloads. Recruitment posters will also be distributed via local primary schools and nurseries. Parents recruited to the trial will be randomised on a 2:1 ratio to intervention or wait-list control conditions (stratified according to child gender and age). The primary outcome measure is positive parenting as measured by a behavioural observation of parent-child interactions using the Dyadic Parent-Child Interaction Coding System [1]. Secondary outcomes include parental report measures of child behaviour, self-reported parental sense of competence, parenting behaviour and parental mental health. Data will be collected at baseline and three months later (post-intervention) for all participants and six months post-baseline for the intervention group only. ANCOVA will be the main statistical method used.

Ethics and dissemination: The trial has received ethical approval from the NHS Betsi Cadwaladr University Health Board Ethics Committee (REC) and the School of Psychology,

Bangor University REC (15/WA/0463). Publications of all outcomes will be in peer-reviewed journals and conference presentations.

Strengths and limitations

- This is a randomised Controlled Trial with a wait-list control group.
- The behavioural observations incorporate inter-rater reliability (20% of all observations at the separate time points).
- Once randomised, intervention parents start the online programme immediately thus reducing the amount of time spent waiting for the intervention.
- A limitation of this study is parents are required to log in each week and engage with the programme, this may result in some parents not fully engaging.

Background

Importance of positive parenting

Children who are at risk of poor outcomes, including impairments in social, emotional and educational functioning [2], often experience harsh and inconsistent parenting from parents who show little positive parental involvement [3]. Problematic parenting strategies can be addressed through teaching positive parenting skills to target such child behaviour problems and achieve positive outcomes [4, 5, 6, 7]. These positive parenting skills that are associated with positive child outcomes are well established and include play, praise, reward, and positive affect [4].

A successful intervention for parents of children with significant behavioural difficulties [6] used mediator analysis to demonstrate that the mechanism for change in child behaviour was

change in parental behaviour [8]. Similarly, teaching positive parental strategies has been shown to increase positive parenting style as measured by direct observation of parent-child interactions [9]. Whilst these studies have focused on programmes for parents of children with, or at risk of, significant problems, there is less evidence for the benefits of parenting programmes for parents in general.

The need for additional parental support

Society is continuously evolving, and although some recent developments have brought about positive changes (such as advances in medical treatments, improvements in working conditions and improved communication), others can present challenges, especially for parents. These can include the challenge of managing children's access to new technological products such as smartphones and video games [10], which can lead to parent-child conflict. Children also spend more time in more sedentary activities such as playing video games and watching television [11] contributing to an epidemic of childhood obesity [12]. Another challenge arises from parental anxiety concerning children playing outside [13] due to increased perception of the risk of danger. Other challenges include the impact of divorce and low socioeconomic status on children's well-being and adjustment [3] as poverty and other disadvantaging circumstances can affect parenting [14].

Children spend increasing amounts of time, between 2-5 hours a day, watching television and for young children this is negatively associated with time spent in creative play [15]. Parents can find it difficult to manage children's access to technology, especially when it is in their bedrooms leading to other difficulties. A survey of 200 parents of children aged 2-13 years found that 67% of children had a television in their bedroom, which was associated with sleep disturbance [16]. Over the past 100 years, there has been a rapid decline in sleep

duration in children and adolescents, on average 0.75 minutes per year [17]. The main reason given by parents for allowing children to have a television in their bedroom was so that adults themselves could watch their own programmes [16]. This results in parents spending less time in the company of their children. This is also true of meal times, with, approximately one third of children younger than six years eating their meals in front of the television reducing opportunities for mealtime social conversation and the development of language skills [18].

Cost implications and service burden associated with problematic child behaviour

Minor child problem behaviours can develop into more significant problems unless addressed while children are still young [19] and there are high costs associated with child mental health and behavioural problems [20]. Conduct problems have a significant impact on children's functioning and quality of life [21] with up to 50% of children and young people with conduct disorder developing antisocial personality disorder [22, 21]. This highlights the importance of providing early universal support to parents to avoid the small behavioural challenges faced by all parents from progressing into more costly ones.

Although, in the UK, there are both universal and targeted services to support families, only 20% of children with mental health difficulties receive specialist child and adolescent mental health services [23]. The majority of families with children at significant risk of poor outcomes are supported by health visitors and school nurses reducing their ability to provide adequate support to all families. A survey of health visitors and school nurses reported that 53% of health visitors saw between 21-50, and 46% of school nurses saw between 50-99 children with emotional or behavioural problems each week [24]. Public policy recognises

the need for early intervention and support for families, but it is not universally available and remains "patchy" [25].

Limitations of group-based and one-to-one parenting interventions

There is strong empirical evidence for the effectiveness of group based preventative behavioural interventions targeting parents of young children at risk of poor outcomes [26, 27, 6, 5, 8]. However, although positive outcomes have been achieved [28], these programmes are not universally available or, when they exist, may not be accessible to some families, especially those living in more rural areas [29] or in poverty [30, 31], for example, the inconvenience of travel to the clinical setting or organising childcare arrangements for groups scheduled during weekday hours can be particularly burdensome [32].

One-to-one parenting interventions have shown good outcomes. Lane and Hutchings [33] recruited health visitors to take part in a 12-session course in behavioural intervention for work with children with behavioural difficulties; each health visitor identified one family to work with. Health visitors demonstrated a significant increase in knowledge of behavioural terminology and reported increased use of the behavioural techniques following the course. Significant improvements for families were also found on measures of child behaviour and maternal mental health [33]. The 'Family Check-up' intervention [34] has also demonstrated good outcomes. The programme involves two or three home visit consultation sessions with the aim of providing more intensive and structured parenting support to those families found to need it. The family-centred intervention significantly predicted improvements in positive behaviour support at child ages 2-3 [34]. However, home-visiting interventions tend to be targeted and can be costly. The mean cost per infant in a trial of the 'Family Nurse Partnership', which targeted vulnerable families totalled £7120 [35]. Similarly, a cost

effective analysis of the Incredible Years basic parenting programme showed that the intervention improved children's behaviour at a cost of £1344 per child [36].

A review of parental and professional perceptions of barriers to parenting interventions [29] highlighted five challenges for both parents and facilitators; (1) situational barriers, (2) psychological barriers including fear of being criticised or stigmatised [37], (3) lack of information/misconception about services, (4) availability of services and (5) poor interagency collaboration. These barriers suggest there could be benefits from alternative modes of programme delivery including behavioural interventions delivered online [38].

Potential benefits of web-based parenting interventions

Technology has the potential to enhance parental engagement, teach key parenting skills, reduce the cost burden associated with group and one-to-one interventions, alleviate pressures on services, particularly those delivered by heath visitors and school nurses, and offer more flexible access [38, 39, 40]. Access to technology is now feasible for many parents due to increased availability of internet access [41]. The number of households with computers increased from 8% to 60% between 1984 and 2003 in the US, and in the UK by 2015, 86% of households had internet access [42]. The majority of parents (75%) now use social media to obtain parent-related information [43] with over eight million people visiting an online parenting information and advice website every month [44].

Although as yet limited in number, web-based programmes for behaviour change (including weight loss and alcohol reduction) have achieved positive outcomes [45, 46], suggesting that technology can be an effective means of providing behaviour change advice and support. Similarly, there is evidence demonstrating increased positive parenting following web-based

interventions [47, 48]. Parents of children aged between 3-12 years with conduct disorder who accessed an online parenting programme, reported less use of harsh parenting and more use of positive praise compared to wait-list control parents [48], and these findings were maintained at the six-month follow-up. However, evidence in this field is currently limited and universal programmes need more evidence to demonstrate effectiveness with families who are not necessarily experiencing significant levels of child problem behaviours. Bayer and colleagues highlighted the importance of offering parental support universally (1) so as not to stigmatise at-risk populations and (2) to prevent missing early signs of problems for families not classified as at-risk [49].

Web based interventions allow parents to access support at home at a time most convenient for their individual family circumstances, eliminating one of the barriers associated with more traditional intervention approaches. The internet allows access to advice without having to seek referral or further advice from health care professionals. This could allow professionals, such as health visitors and school nurses, more time and resources to target clinical (or identified at-risk) populations with more individualised interventions. Providing parents access to online advice and support could increase parental understanding of how to promote positive child development and potentially prevent the development of child behaviour problems. Providing positive parenting support in general could avoid the intergenerational transfer of poor parenting practices [25].

Rationale

The aim of the web based parenting programme, based on 'The Little Parent Handbook' [50], is to provide information and activities based on core social learning theory principles associated with positive parenting practices and good child outcomes to parents of children

aged 3-8 years. The study will explore parental satisfaction and engagement with the programme and whether it is effective in demonstrating increased use of positive parental practices in parents of children with a wide age range and varying behavioural patterns.

Aims and Objectives

The aim of this trial is to conduct a pilot randomised controlled trial (RCT) on the effectiveness of an online parenting programme, for parents of children aged 3-8 years who would like to learn more about positive parenting by comparing outcomes for intervention and wait-list control groups.

The key objectives are to establish whether parents find the programme acceptable; whether the programmes successfully engages and retains parents; whether the programme produces statistically significant increases in positive parenting as observed in a parent-child observation when compared to wait-list control parents; and to determine whether the online programme produces any changes in secondary outcomes (parent-reported child behaviour, parent self-reported sense of competence, behaviour and mental health). The study hypotheses are:

i. the online parenting programme will lead to significant increases in positive parenting strategies as displayed in the behavioural observation coded using Dyadic Parent-Child Interaction Coding System [1]

ii. the online programme will significantly increase positive behaviours and mental health of parents, including self-reported parenting skills, parental sense of competence and parental mental health

iii. the online programme will lead to reduction in parent-reported levels of child problem behaviour as reported using the Eyberg Child Behaviour Inventory [51]

Methods/Design

Trial design

This pilot RCT will explore the effectiveness of an online parenting programme. Parents of children aged 3-8 years who would like to learn more about positive parenting will be randomly allocated to the intervention condition with immediate access to the programme or to a 3-month wait-list control group on a 2:1 ratio.

Setting

Self-report and observational data will be collected in parents' homes during home visits and parents will access the programme at home. The programme encourages parents to practice the behavioural skills covered in the programme at home with their child.

Participants

Parents of children aged 3-8 years who would like to learn more about positive parenting, in particular how to encourage positive child behaviour through praise and reward, are invited to participate in the study.

Eligibility Criteria

Inclusion criteria.

To be eligible for the study parents must have a child aged between 3-8 years, be able to understand English (as the programme is only currently available in English) and be able to access the internet on a PC, laptop, iPad or tablet. The software does not yet support smartphones.

Exclusion criteria.

Parent does not have a child aged between 3-8 years, does not understand English and does not have access to the internet.

Recruitment

Health visitors and school nurses in Gwynedd and Anglesey (North-West Wales) will approach parents of children aged 3-8 years on their own caseloads and describe the online programme and the research trial. If parents decide that they might want to sign up for the study, they will be asked by the health visitor/school nurse to complete a note of interest form, that will be sent to the research office at Bangor University, giving consent for a member of the research team to contact the parent.

On receipt of the note of interest form, a member of the research team will contact the parent to arrange a convenient time to visit and discuss the project further. The researcher will go through the information sheet with the parent during this home visit and ensure that any questions are answered. If the parent is happy to continue, the researcher will obtain informed consent from the parent to participate in the study. Only when consent has been obtained will the researcher proceed to ask the parent to fill out the self-report measures and take part in a 30-minute behavioural observation of parent-child interaction.

In addition to health visitors and school nurses approaching parents on their caseloads, recruitment posters will be distributed in primary schools and nurseries in Gwynedd, Anglesey, Conwy and Denbighshire. An e-mail address and a contact telephone number will be provided on the recruitment poster so that interested parents can contact the research team

directly. Parents will either be sent a detailed information sheet via e-mail or the researcher will discuss the research in depth over the telephone. If parents would still like to participate, arrangements will then be made for a home visit to discuss the study further. Similarly, parents who hear about the study through word of mouth can contact the research team for further information regarding the trial.

Intervention

Origins of 'The Little Parent Handbook'

Trials conducted by Hutchings and colleagues during the 1990s [31, 52] with parents and health visitors demonstrated positive outcomes from teaching effective behavioural strategies to parents of children with challenging behavior for both clinically referred and pre-school prevention populations. Significant overall improvements were found for intervention families on measures of child behaviour, parenting practices and maternal mental health [31] [33]. As part of these trials intervention parents were provided with help sheets that were subsequently published as 'The Little Parent Handbook' [50]. These trials were multi-component trials and so it is difficult to establish the true extent of the effectiveness of the parent help-sheets, however they contained the evidence based behavioural principles on which the interventions were based.

LifeGuide online behaviour change software

The LifeGuide software, developed at the University of Southampton [53], was used in the creation of the online parenting programme. The aim of LifeGuide is to continuously develop, evaluate and disseminate a set of tools that will allow researchers to flexibly create and modify online behaviour change interventions [54]. LifeGuide software allows

researchers to deliver behavioural principles both through programme delivery (text message prompts etc.) and programme content (The Little Parent Handbook).

Features of the online parenting programme include automated feedback based on individual performance, online praise messages for spending time with their child, text message reminders to access the next session, and multiple-choice quizzes to test knowledge. The programme also enables the collection of individual usage data (which can be extracted into Microsoft Excel).

The Little Parent Handbook Online Programme

The programme introduces evidence-based behavioural principles that have been shown to be effective in strengthening parent-child relations through encouraging positive child behaviour [55]. A feasibility study of the online parenting programme at the end of 2015 provided user feedback prior to conducting this larger-scale RCT trial. Overall, feedback was very positive with the majority of participants reporting that they would recommend the programme to parents of children aged 3-8 years. Minor modifications were made based on the feedback, these include text message prompting parents to log-in to subsequent sessions, more video examples of positive parenting and the option to look back over previously completed chapters again. The intervention consists of ten chapters, eight content and two revision chapters. The topics are:

i. Spending special time with your child through play
ii. Encouraging good behaviour through praising
iii. Encouraging good behaviour through rewarding
iv. How to get better at giving instructions [part 1]
v. How to get better at giving instructions [part 2]

vi. Revision

vii. Ignoring problem behaviour

viii. Teaching your child new behaviours

ix. How to develop your child's language skills

x. Revision

Intervention parents will be provided with a link to the website and a username and password. Contact details of an administrator will be provided in case any parent requires technical support during the programme. Parents will be asked to log in and complete one chapter each week, each chapter will take approximately thirty minutes to complete. The software ensures that parents have completed each chapter before they can move on to the next one; they are not required to complete the chapter in one sitting. Log in details allow parents to access the programme as many times as they wish. The intervention has been programmed to take parents to the last page that they viewed on the next occasion that they log in to avoid parents having to start the programme from the beginning. In order to give parents sufficient time to practice the principles outlined in the individual chapters, the intervention has been programmed so that there will be a minimum five-day gap between each chapter. If parents log in before the five days have elapsed, they will be offered the opportunity to look back over previously completed chapters again.

The programme asks parents to practice the skills presented in the chapter with their child at home. Each chapter concludes with a suggested practice activity. Parents are also encouraged to keep paper records detailing their activities (a research team member will collect all paper copies at the end of the intervention). Parents can also record online each week how many times they have played with their child by selecting the amount of times from a drop-down menu. The programme encourages parents to spend more time playing with their child in

order to strengthen their relationship, and they are continuously reminded to engage in this activity throughout the programme both by praise messages and by being prompted to record the amount of time spent playing. A praise message congratulates the parent for spending time with their child if they report spending time with their child during the past week, or since the last time they logged in. If parents do not report having spent time with their child during the past week, a prompt message appears reminding them of the importance of this activity.

Each chapter covers an individual behavioural principle that aims to strengthen the parent-child relationship. Parents read through information (or listen via an audio button if they prefer) and watch video examples of positive parenting. The video clips are short in length (all are less than one minute long) allowing the opportunity for multiple viewing. At the end of each chapter there is a longer video and parents are asked to answer three questions based on the video clip (by selecting yes or no) in order to develop their observational skills and to encourage them to identify positive child behaviours. For example, at the end of chapter two (praising positive behaviour) parents are prompted to watch a video of a parent giving her child a specific labelled praise, and then answering three questions based on the video; (1) Did the parent praise the child immediately? (2) Was the parent close to the child when praising? (3) Did the parent share positive feelings when praising? A score out of three and the correct answers are provided for the responses to the videos.

Each chapter ends with a multiple-choice quiz to test parents' knowledge and understanding of key principles. Parents will be given online automated feedback on their quiz scores in addition to the correct answers. Parents also have an option to download and print a summary sheet for each chapter.

Parents will be given an opportunity to receive text message prompts to help keep them on track. If they would like to receive text messages, they will be asked at the beginning of the programme to enter their mobile phone number. The programme is fully automated, and the research team will have no contact with parents during the intervention. The centre administrator can be contacted if parents require any technical assistance during the study. A text message will be sent five days after the completion of a chapter informing the parent that the next chapter is now available. If the parent has not logged into the programme to complete the next chapter three days after it becomes available, a reminder text will be sent prompting them to log in and complete the next chapter. If a parent still has not logged in, weekly reminders will be sent.

Baseline data will be collected prior to randomisation and, once it is completed, intervention parents will receive a notification of their status and their log in details, whilst parents in the wait-list control group will be informed that they will have access to the programme after three months. Follow up data will be collected after three moths regardless of whether intervention parents have completed the programme. Once post-intervention data has been collected, control group parents will receive their log in details for the programme. On completion of both baseline and follow-up visits, families will receive a children's book as a thank you for their time. On completion of all measures, all parents will receive a copy of 'The Little Parent Handbook'. Data collection will begin in April 2016 and end in February 2017.

Study Outcomes

Primary outcome.

The primary outcome is to establish whether the online parenting programme produces significant changes in positive parenting practices from baseline to follow-up as recorded using the DPICS. The researcher will observe the parent and child engaging in child-led play for thirty minutes. This coding system was specifically designed to assess the quality of parent-child social interaction [56]. The DPICS has demonstrated high inter-rater reliability for parent and child behaviours, $r = 0.67$ to 1.0 and $r = 0.76$ to 1.0 respectively [56]. Direct observation was selected as the primary outcome as direct observational methods provide a more precise account of behaviour defined by the researcher and not the parent [57]. Additionally, this observational measure has been used in a number of previous studies at the centre [6, 52, 58].

There are eight DPICS parent categories summarised in terms of positive and negative parenting. Positive parenting categories comprise of direct command, labelled praise, unlabelled praise and descriptive commenting/verbal labelling. Negative parenting categories comprise of indirect command, questions, critical statement and negative command. No child categories will be recorded, as child behaviour will be measured using the parent report ECBI. Observational coding is continuous and records the total frequency of each category of parent behaviour for a total of thirty minutes. Inter-rater levels of reliability will be assessed for 20% of all observations at all three-time points.

Secondary outcomes.

The following secondary outcomes will be collected at the three time points by the research team for the intervention group and twice for the wait-list control group.

- Child behaviour as measured by the Eyberg Child Behaviour Inventory [1]. This measure is a 36-item inventory completed by the parent to assess the frequency and

intensity of child behavioural problems for children aged 2-16 years, and has been used in many previous trials including several that have been conducted at the centre [6] [31]. Factor analyses of the ECBI for both children and adolescents indicate that it is a uni-dimensional measure of conduct problem behaviours [51].

- Parenting practices as measured by the Arnold O'Leary Parenting Scale [59]. This is a 30-item inventory with three subscales measuring parental behaviour: laxness, over-reactivity and verbosity. Responses are recorded on a seven-point scale with two alternative responses to a particular parental situation. The parenting scale has been shown to exhibit adequate internal validity and test-retest reliability [59] in addition to demonstrating significant correlations with observational measures of child problem behaviour [59].
- Parental confidence as measured by the Parental Sense of Competence questionnaire [60]. This 17-item likert–scale questionnaire measures competence on two separate dimensions: satisfaction and efficacy. The satisfaction questions measure parental anxiety, motivation and frustration (for example, 'sometimes I feel like I'm not getting anything done') and the efficacy question examine competence, capability levels and problem-solving skills (for example, 'I meet my own personal expectations for expertise in caring for my child') in relation to parenting [60]. Ohan, Leung and Johnston [61] replicated the factor structure of the Parenting Sense of Competence Scale produced by Johnston and Mash [60], and provided evidence that the satisfaction and efficacy scales from this measure assess distinct aspects of parenting self-esteem.
- Parental mental health as measured by the General Health Questionnaire [62]. This is a 30-item questionnaire and each item invites one of four responses in order to assess psychiatric symptoms including social dysfunction, sleeping patterns and depression

[63]. The responses include 'better than usual', 'same as usual', 'less than usual' and 'much less than usual' to questions such as 'have you found everything getting on top of you?' and 'have you been getting edgy and bad tempered?' This measure was used as research has demonstrated the association between maternal mental health and child conduct problems [64]. Reliability coefficients of the questionnaire have ranged from 0.78 to 0.95 in various studies [65]. There have been several factor analyses of the GHQ-30 in relatively large community samples [63].

Demographic information

Demographic information will be collected from all participants at baseline prior to randomisation. The demographic questionnaire is based on the 'Personal Development and Health Questionnaire' [30] and will include data on socioeconomic status, including poverty, parental educational level and single-parent status. The questionnaire will cover the following information:

- Age of parent and child, gender of parent and child, child diagnosis, parent's relationship to the child (biological or non-biological parent), parent's age at birth of first child, how many children the parent has, ages of all children, parent's current relationship status, partner's relationship to the child, housing situation, employment status, income, parent's level of education and whether they have previously attended a parenting course. An additional question regarding their internet usage is also included.

Mediators

Potential mediators of change in child behaviour will be explored to establish whether any changes in parenting behaviour are associated with changes in child behaviour using the parent report of child behaviour as measured by the ECBI as the outcome of interest. Potential mediators of change in parenting behaviour will be explored using the DPICS observation instrument and the Arnold O'Leary parenting scale, mental health questionnaire and parent sense of competence questionnaire.

Moderators

Potential moderators, or an analysis of for whom the intervention worked best, will be explored using data from the demographic questionnaire. These will include poverty, unemployment, housing situation, and single parent status, level of parental education and level of child behaviour problems as reported by the ECBI. Child age and gender are also potential moderators.

Data Collection

Members of the research team will collect parental self-report measures and observational data on parent-child interaction using the DPICS behaviour coding system, during home visits. Parents will also be asked to complete a short feedback/satisfaction questionnaire at the end of the study to share their views of the programme.

The DPICS has been used in a number of studies evaluating parenting programmes [6, 59, 65]. Research team members are already trained in DPICS coding and have reached 80% inter-rater reliability across all categories. At least two coders, to establish inter-rater reliability, will code 20% of observations at each time-point simultaneously (baseline and follow-up). Frequent practice sessions and meetings will be held to discuss any matters

arising and to ensure maintenance of a minimum level of 80% reliability.

Sample Size

The intention is to recruit 60 parents (40 to intervention and 20 to wait-list control, randomised on a 2:1 ratio). Due to limited funds and time restrictions associated with recruitment and data collection, a larger sample size would be difficult to recruit. This is a pilot RCT study and is exploratory in nature; and a sample size of 60 parents should be sufficient to explore initial outcomes in terms of programme acceptability, effectiveness and encouragement in the use of positive parental strategies.

Randomisation

Once all of the data for individual parents have been collected at baseline, parents will be randomised to either the intervention or a wait-list control condition on a 2:1 ratio. This allows for the evaluation of a larger intervention sample whilst also reducing the number of parents waiting for the intervention. This design is favoured for research in this field [6]. The randomisation will be stratified according to child age (3-5 and 6-8 years old) and gender (male and female) using the online software 'sealed envelope'. The centre administrative assistant will undertake the randomisation process, which will require entering the participant identification number, child age and child gender. The software will then generate the decision on whether the participant has been allocated to the intervention (group 1) or control (group 2) condition. Parents will receive a letter from the administrator informing them of their group allocation and intervention parents will receive the link to the website and their log in details with this letter. Control parents will be informed that they will receive their log in details upon completion of the second home visit (post-intervention data).

Blinding

Baseline measures will be completed prior to randomisation and parents will be asked (during home visits) not to reveal their group allocation to researchers in order, as far as possible, to keep the researchers blind to parent group allocation. However, some parents may reveal their allocation during the first follow-up home visits. In this instance, researchers will make a record of this. Due to the design of the study, it will not be possible to keep the researchers blind to group allocation at the second six-month follow-up stage as they will only involve intervention parents. However the key measures are parent report questionnaires and the frequency based behavioural observation that incorporates inter-rater reliability. If high levels of unmasking occur, a variable will be added to the analysis to control for this.

Statistical Analysis

Baseline characteristics for all parents and children will be analysed and checked for differences (if any) between the intervention and wait-list control groups. Any differences will be recorded and accounted for the in the analysis. ANCOVA will be used as the main analysis method to compare the intervention and wait-list control groups. A regression analysis will be used to analyse potential effects of mediator and moderator effects. Missing data will be treated using appropriate statistical methods e.g. multiple imputation.

Discussion

This trial will provide information on the effectiveness of an online parenting programme, an intervention designed to increase positive parenting for parents of children aged 3-8 years. The effects of the intervention on child behaviour, parenting behaviour, parental mental health and parental sense of competence will also be assessed. This project is timely when considering the current situation with regards to rising numbers of children displaying

behaviour problems [21], the increasing challenges faced by parents [10] and the known impact of parenting style on the establishment and maintenance child behaviour problems [65, 8, 50]. Additionally, this online programme targets intervention barriers, as parents can complete the web-based programme at home at a convenient time without relying on referrals from professionals.

This intervention has the potential to be a cost-effective early intervention prevention resource both for parents for whom no support would otherwise be available and/or as an alternative cost effective resource for use by the health care services [67]. An evidence-based online intervention could allow professionals to spend more time and resources supporting families with more significant problems, by enabling parents who require general parenting support to access a web-based programme. This could potentially reduce the number of families seeking advice for whom no service currently exists [32].

Proposed results

This evaluation of a web version of a parenting programme based on 'The Little Parent Handbook', which itself includes material developed as part of an evidence-based intervention, should be a useful addition to the parenting literature. If significant benefits are found, the intervention could be made available for health visitors and school nurses to distribute to parents on a regular basis. It is hypothesised that the online programme will encourage parents to use positive parenting strategies, including spending more time with their child and praising and rewarding positive child behaviour. Additionally, it is hypothesised that the online programme will improve a range of outcomes including self-reported parenting practices, parental mental health, parental confidence and child behaviour.

Trial registration: Current Controlled Trials ISRCTN89370147 (May 5th 2016).

Trial status

The trial is currently on going. Baseline measures commenced in April 2016 and 3-month follow-up are commencing in July 2016.

Abbreviations

NICE: The National Institute for Health and Care Excellence; ONS: Office for National Statistics, ANCOVA; Analysis of Covariance; REC: Research Ethics Committee

Author's contributions

DAO: designing of the online programme, manuscript writing, gaining ethical approval, data collection, data analysis, critical revision and final approval of manuscript. NG: critical revision and final approval of manuscript. JH: author of 'The Little Parent Handbook', critical revision and final approval of manuscript.

Competing interests: The third author [JH] is the author of 'The Little Parent Handbook.

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SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description
Administrative information		
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym □
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry □
	2b	All items from the World Health Organization Trial Registration Data Set
Protocol version	3	Date and version identifier
Funding	4	Sources and types of financial, material, and other support □
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors □
	5b	Name and contact information for the trial sponsor □
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities □
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)
Introduction		
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention □
	6b	Explanation for choice of comparators □
Objectives	7	Specific objectives or hypotheses □
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) □

Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained □
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) □
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered □
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) **N/A**
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) **N/A**
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial **N/A**
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended □
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) □
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations □
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size □

Methods: Assignment of interventions (for controlled trials)

Allocation:

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions □

Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned □
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions □
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how □
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial □
Methods: Data collection, management, and analysis		
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol □
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols □
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol □
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol □
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses) □
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) □
Methods: Monitoring		
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed

	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor
Ethics and dissemination		
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval □
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) □
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable □
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial □
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site □
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions
	31b	Authorship eligibility guidelines and any intended use of professional writers
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code

Appendices

Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable **N/A**

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

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Evaluation of an online parenting programme based on 'The Little parent Handbook': Study protocol for a pilot randomised controlled trial

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Title: Evaluation of an online parenting programme based on 'The Little Parent Handbook': Study protocol for a pilot randomised controlled trial

Authors: Dawn Adele Owen, Nia Griffith, Judy Hutchings

Author details:

Centre for Evidence Based Early Intervention, School of Psychology, Nantlle Building, Normal Site, Bangor University, Bangor, Gwynedd, LL57 2PZ, UK (01248 383 758).

Email: dawn.a.owen@bangor.a.uk

School of Psychology, Wheldon Building, Room 113, Bangor University, Bangor, Gwynedd, LL57 2PZ, UK.

Email: n.griffith@bangor.ac.uk

Centre for Evidence Based Early Intervention, School of Psychology, Nantlle Building, Normal Site, Bangor University, Bangor, Gwynedd, LL57 2PZ, UK.

Email: j.hutchings@bangor.ac.uk

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Abstract

Introduction: The online parenting programme based on 'The Little Parent Handbook' is a web-based parenting intervention for parents of children aged 3-8 with an interest in positive parenting. The programme focuses on strengthening parent-child relationships through encouraging positive child behaviour. This trial will evaluate whether the intervention is effective in increasing the use of positive parenting strategies outlined in the programme using parent report and blind observation.

Methods and analysis: This is a pilot randomised controlled trial with intervention and wait-list control conditions. The intervention is a ten-week online parenting programme to promote positive parent-child relations by teaching core social learning theory principles that encourage positive child behaviour, primarily through the use of praise and rewards. Health visitors and school nurses will circulate a recruitment poster to parents of children aged 3-8 years on their current caseloads. Recruitment posters will also be distributed via local primary schools and nurseries. Parents recruited to the trial will be randomised on a 2:1 ratio to intervention or wait-list control conditions (stratified according to child gender and age). The primary outcome measure is positive parenting as measured by a behavioural observation of parent-child interactions using the Dyadic Parent-Child Interaction Coding System [1]. Secondary outcomes include parental report measures of child behaviour, self-reported parental sense of competence, parenting behaviour and parental mental health. Data will be collected at baseline and three months later (post-intervention) for all participants and six months post-baseline for the intervention group only. ANCOVA will be the main statistical method used.

Ethics and dissemination: The trial has received ethical approval from the NHS Betsi Cadwaladr University Health Board Ethics Committee (REC) and the School of Psychology,

Bangor University REC (15/WA/0463). Publications of all outcomes will be in peer-reviewed journals and conference presentations.

Trial registration: Current Controlled Trials ISRCTN89370147 (May 5th 2016).

Strengths and limitations

- This is a randomised Controlled Trial with a wait-list control group.
- The behavioural observations incorporate inter-rater reliability (20% of all observations at the separate time points).
- Once randomised, intervention parents start the online programme immediately thus reducing the amount of time spent waiting for the intervention.
- A limitation of this study is parents are required to log in each week and engage with the programme, this may result in some parents not fully engaging and the potential loss of follow-up data.
- Due to time and funding constraints, this trial aims to enroll sixty parents, which is a fairly small sample size.
- Funding and time constraints do not allow for a longer-term follow-up.

Background

Minor child problem behaviours can develop into more significant problems unless addressed while children are still young [2] and there are high costs associated with child mental health and behavioural problems [3]. Conduct problems have a significant impact on children's functioning and quality of life [4] with up to 50% of children and young people with conduct disorder developing antisocial personality disorder [5, 4]. This highlights the importance of providing early universal support to parents to avoid the small behavioural challenges faced by all parents from progressing into more costly ones.

Children who are at risk of poor outcomes, including impairments in social, emotional and educational functioning [6], often experience harsh and inconsistent parenting from parents who show little positive parental involvement [7]. Problematic parenting strategies can be addressed through teaching positive parenting skills to target such child behaviour problems and achieve positive outcomes [8, 9, 10, 11]. These positive parenting skills that are associated with positive child outcomes are well established and include play, praise, reward, and positive affect [8].

A successful intervention for parents of children with significant behavioural difficulties [10] used mediator analysis to demonstrate that the mechanism for change in child behaviour was change in parental behaviour [12]. Similarly, teaching positive parental strategies has been shown to increase positive parenting style as measured by direct observation of parent-child interactions [13]. Whilst these studies have focused on programmes for parents of children with, or at risk of, significant problems, there is less evidence for the benefits of parenting programmes for parents in general. Public policy recognises the need for early intervention and support for families, but it is not universally available and remains "patchy" [14].

In the UK, the National Institute for Health and Care Excellence [4] identified the Incredible Years Parent Programme as a treatment for conduct disorder [15], and this evidence-based programme was introduced to North West Wales through the NHS Child and Adolescent Mental Health Service in the 1990s (CAMHS) [15]. Numerous Randomised Controlled Trials have shown significant improvements for child behaviour following the intervention [10, 16]. However, these programmes are not readily available. The Flying Start initiative offers parenting programmes on an annual basis to families living in disadvantages areas with a child aged four years or younger [17], and may not be accessible to some families due to barriers [18] for example, the inconvenience of travel to the clinical setting or organising

childcare arrangements for groups scheduled during weekday hours can be particularly burdensome [19]. Additionally, these programmes can be costly as an effective analysis of the Incredible Years basic parenting programme showed that the intervention improved children's behaviour at a cost of £1344 per child [20].

Challenges in the availability of parenting programmes has resulted in health visitors and school nurses supporting the majority of families in the UK with children at significant risk of poor outcomes, reducing their ability to provide adequate support to all families. A survey of health visitors and school nurses reported that 53% of health visitors saw between 21-50, and 46% of school nurses saw between 50-99 children with emotional or behavioural problems each week [21]. A review of parental and professional perceptions of barriers to parenting interventions [18] highlighted five challenges for both parents and facilitators; (1) situational barriers, (2) psychological barriers including fear of being criticised or stigmatised [22], (3) lack of information/misconception about services, (4) availability of services and (5) poor interagency collaboration. These barriers suggest there could be benefits from alternative modes of programme delivery including behavioural interventions delivered online [23].

Technology has the potential to enhance parental engagement, teach key parenting skills, reduce the cost burden associated with group and one-to-one interventions, alleviate pressures on services, particularly those delivered by heath visitors and school nurses, and offer more flexible access [23, 24, 25]. Access to technology is now feasible for many parents due to increased availability of internet access [26]. The number of households with computers increased from 8% to 60% between 1984 and 2003 in the US, and in the UK by 2015, 86% of households had internet access [27]. The majority of parents (75%) now use

social media to obtain parent-related information [28] with over eight million people visiting an online parenting information and advice website every month [29].

Although as yet limited in number, web-based programmes for behaviour change (including weight loss and alcohol reduction) have achieved positive outcomes [30, 31], suggesting that technology can be an effective means of providing behaviour change advice and support. Similarly, there is evidence demonstrating increased positive parenting following web-based interventions [32, 33]. Parents of children aged between 3-12 years with conduct disorder who accessed an online parenting programme, reported less use of harsh parenting and more use of positive praise compared to wait-list control parents [33], and these findings were maintained at the six-month follow-up. However, evidence in this field is currently limited and universal programmes need more evidence to demonstrate effectiveness with families who are not necessarily experiencing significant levels of child problem behaviours. Bayer and colleagues highlighted the importance of offering parental support universally (1) so as not to stigmatise at-risk populations and (2) to prevent missing early signs of problems for families not classified as at-risk [34].

Web based interventions allow parents to access support at home at a time most convenient for their individual family circumstances, eliminating one of the barriers associated with more traditional intervention approaches. The internet allows access to advice without having to seek referral or further advice from health care professionals. This could allow professionals, such as health visitors and school nurses, more time and resources to target clinical (or identified at-risk) populations with more individualised interventions. Providing parents access to online advice and support could increase parental understanding of how to promote positive child development and potentially prevent the development of child

behaviour problems. Providing positive parenting support in general could avoid the intergenerational transfer of poor parenting practices [14].

Rationale

The aim of the web based parenting programme, based on 'The Little Parent Handbook' [35], is to provide information and activities based on core social learning theory principles associated with positive parenting practices and good child outcomes to parents of children aged 3-8 years. The study will explore parental satisfaction and engagement with the programme and whether it is effective in demonstrating increased use of positive parental practices in parents of children with a wide age range and varying behavioural patterns.

Aims and Objectives

The aim of this trial is to conduct a pilot randomised controlled trial (RCT) on the effectiveness of an online parenting programme, for parents of children aged 3-8 years who would like to learn more about positive parenting by comparing outcomes for intervention and wait-list control groups.

The key objectives are to establish whether the programmes successfully engages and retains parents; whether the programme produces statistically significant increases in positive parenting as observed in a parent-child observation when compared to wait-list control parents; and to determine whether the online programme produces any changes in secondary outcomes (parent-reported child behaviour, parent self-reported sense of competence, behaviour and mental health). The study hypotheses are:

i. the online parenting programme will lead to significant increases in positive parenting strategies as displayed in the behavioural observation coded using Dyadic Parent-Child Interaction Coding System [1]

ii. the online programme will significantly increase positive behaviours and mental health of parents, including self-reported parenting skills, parental sense of competence and parental mental health

iii. the online programme will lead to reduction in parent-reported levels of child problem behaviour as reported using the Eyberg Child Behaviour Inventory [36]

Methods/Design

Trial design

This pilot RCT will explore the effectiveness of an online parenting programme. Parents of children aged 3-8 years who would like to learn more about positive parenting will be randomly allocated to the intervention condition with immediate access to the programme or to a 3-month wait-list control group on a 2:1 ratio.

Setting

Self-report and observational data will be collected in parents' homes during home visits and parents will access the programme at home. The programme encourages parents to practice the behavioural skills covered in the programme at home with their child.

Participants

Parents of children aged 3-8 years who would like to learn more about positive parenting, in particular how to encourage positive child behaviour through praise and reward, are invited to participate in the study.

Eligibility Criteria

Inclusion criteria.

To be eligible for the study parents must have a child aged between 3-8 years, be able to understand English (as the programme is only currently available in English) and be able to access the internet on a PC, laptop, iPad or tablet. The software does not yet support smartphones. Parents who are currently receiving support from services are also invited to participate (they will be asked to record which services they are receiving and the duration).

Exclusion criteria.

Parent does not have a child aged between 3-8 years, does not understand English and does not have access to the internet.

Recruitment

Health visitors and school nurses in Gwynedd and Anglesey (North-West Wales) will approach parents of children aged 3-8 years on their own caseloads and describe the online programme and the research trial. If parents decide that they might want to sign up for the study, they will be asked by the health visitor/school nurse to complete a note of interest form, that will be sent to the research office at Bangor University, giving consent for a member of the research team to contact the parent.

On receipt of the note of interest form, a member of the research team will contact the parent to arrange a convenient time to visit and discuss the project further. The researcher will go through the information sheet with the parent during this home visit and ensure that any questions are answered. If the parent is happy to continue, the researcher will obtain informed consent from the parent to participate in the study. Only when consent has been obtained will

the researcher proceed to ask the parent to fill out the self-report measures and take part in a 30-minute behavioural observation of parent-child interaction.

In addition to health visitors and school nurses approaching parents on their caseloads, recruitment posters will be distributed in primary schools and nurseries in Gwynedd, Anglesey, Conwy and Denbighshire. An e-mail address and a contact telephone number will be provided on the recruitment poster so that interested parents can contact the research team directly. Parents will either be sent a detailed information sheet via e-mail or the researcher will discuss the research in depth over the telephone. If parents would still like to participate, arrangements will then be made for a home visit to discuss the study further. Similarly, parents who hear about the study through word of mouth can contact the research team for further information regarding the trial.

It is expected that both forms of recruitment (poster and health visitor/ school nurse) will attract parents from varying socioeconomic backgrounds who are experiencing varying levels of child problem behaviour. For the purpose of this pilot trial, baseline characteristics of all parents will be reported and compared with the population as a whole. Additionally, the percentage of parents recruited from each source will be reported and their characteristics compared in order to explore the effects of the intervention for the whole sample.

Intervention

Origins of 'The Little Parent Handbook'

Trials conducted by Hutchings and colleagues during the 1990s [37, 38] with parents and health visitors demonstrated positive outcomes from teaching effective behavioural strategies to parents of children with challenging behavior for both clinically referred and pre-school

prevention populations. Significant overall improvements were found for intervention families on measures of child behaviour, parenting practices and maternal mental health [37, 39]. As part of these trials intervention parents were provided with help sheets that were subsequently published as 'The Little Parent Handbook' [35]. These trials were multi-component trials and so it is difficult to establish the true extent of the effectiveness of the parent help-sheets, however they contained the evidence based behavioural principles on which the interventions were based.

LifeGuide online behaviour change software

The LifeGuide software, developed at the University of Southampton [40], was used in the creation of the online parenting programme. The aim of LifeGuide is to continuously develop, evaluate and disseminate a set of tools that will allow researchers to flexibly create and modify online behaviour change interventions [41]. LifeGuide software allows researchers to deliver behavioural principles both through programme delivery (text message prompts etc.) and programme content (The Little Parent Handbook).

Features of the online parenting programme include automated feedback based on individual performance, online praise messages for spending time with their child, text message reminders to access the next session, and multiple-choice quizzes to test knowledge. The programme also enables the collection of individual usage data (which can be extracted into Microsoft Excel).

The Little Parent Handbook Online Programme

The programme introduces evidence-based behavioural principles that have been shown to be effective in strengthening parent-child relations through encouraging positive child behaviour

[42]. A small-scale feasibility study of the online parenting programme was conducted at the end of 2015 with the aim of providing user feedback prior to conducting this larger-scale RCT trial. This study had no measures and participants were not randomised, instead twenty participants were asked to complete the intervention and fill out a feedback form. Overall, feedback was very positive with the majority of participants reporting that they would recommend the programme to parents of children aged 3-8 years. Minor modifications were made based on the feedback, these include text message prompting parents to log-in to subsequent sessions, more video examples of positive parenting and the option to look back over previously completed chapters again. The intervention consists of ten chapters, eight content and two revision chapters. The topics are:

i. Spending special time with your child through play
ii. Encouraging good behaviour through praising
iii. Encouraging good behaviour through rewarding
iv. How to get better at giving instructions [part 1]
v. How to get better at giving instructions [part 2]
vi. Revision
vii. Ignoring problem behaviour
viii. Teaching your child new behaviours
ix. How to develop your child's language skills
x. Revision

Intervention parents will be provided with a link to the website and a username and password. Contact details of an administrator will be provided in case any parent requires technical support during the programme. Parents will be asked to log in and complete one chapter each week, each chapter will take approximately thirty minutes to complete. The software ensures that parents have completed each chapter before they can move on to the

next one; they are not required to complete the chapter in one sitting. Log in details allow parents to access the programme as many times as they wish. The intervention has been programmed to take parents to the last page that they viewed on the next occasion that they log in to avoid parents having to start the programme from the beginning. In order to give parents sufficient time to practice the principles outlined in the individual chapters, the intervention has been programmed so that there will be a minimum five-day gap between each chapter. If parents log in before the five days have elapsed, they will be offered the opportunity to look back over previously completed chapters again.

The programme asks parents to practice the skills presented in the chapter with their child at home. Each chapter concludes with a suggested practice activity. Parents are also encouraged to keep paper records detailing their activities. Parents can also record online each week how many times they have played with their child by selecting the amount of times from a drop-down menu. The programme encourages parents to spend more time playing with their child in order to strengthen their relationship, and they are continuously reminded to engage in this activity throughout the programme both by praise messages and by being prompted to record the amount of time spent playing. A praise message congratulates the parent for spending time with their child if they report spending time with their child during the past week, or since the last time they logged in. If parents do not report having spent time with their child during the past week, a prompt message appears reminding them of the importance of this activity.

Each chapter covers an individual behavioural principle that aims to strengthen the parent-child relationship. Parents read through information (or listen via an audio button if they prefer) and watch video examples of positive parenting. The video clips are short in length

(all are less than one minute long) allowing the opportunity for multiple viewing. At the end of each chapter there is a longer video and parents are asked to answer three questions based on the video clip (by selecting yes or no) in order to develop their observational skills and to encourage them to identify positive child behaviours. For example, at the end of chapter two (praising positive behaviour) parents are prompted to watch a video of a parent giving her child a specific labelled praise, and then answering three questions based on the video; (1) Did the parent praise the child immediately? (2) Was the parent close to the child when praising? (3) Did the parent share positive feelings when praising? A score out of three and the correct answers are provided for the responses to the videos.

Each chapter ends with a multiple-choice quiz to test parents' knowledge and understanding of key principles. Parents will be given online automated feedback on their quiz scores in addition to the correct answers. Parents also have an option to download and print a summary sheet for each chapter.

Parents will be given an opportunity to receive text message prompts to help keep them on track. If they would like to receive text messages, they will be asked at the beginning of the programme to enter their mobile phone number. The programme is fully automated, and the research team will have no contact with parents during the intervention. The centre administrator can be contacted if parents require any technical assistance during the study. A text message will be sent five days after the completion of a chapter informing the parent that the next chapter is now available. If the parent has not logged into the programme to complete the next chapter three days after it becomes available, a reminder text will be sent prompting them to log in and complete the next chapter. If a parent still has not logged in, weekly reminders will be sent.

Baseline data will be collected prior to randomisation and, once it is completed, intervention parents will receive a notification of their status and their log in details, whilst parents in the wait-list control group will be informed that they will have access to the programme after three months. Follow up data will be collected after three moths regardless of whether intervention parents have completed the programme. Once post-intervention data has been collected, control group parents will receive their log in details for the programme. On completion of both baseline and follow-up visits, families will receive a children's book as a thank you for their time. On completion of all measures, all parents will receive a copy of 'The Little Parent Handbook'. Data collection will begin in April 2016 and end in February 2017.

Study Outcomes

Primary outcome

The primary outcome is to establish whether the online parenting programme produces significant changes in positive parenting practices from baseline to follow-up as recorded using the DPICS. The researcher will observe the parent and child engaging in child-led play for thirty minutes. This coding system was specifically designed to assess the quality of parent-child social interaction [43]. The DPICS has demonstrated high inter-rater reliability for parent and child behaviours, $r = 0.67$ to 1.0 and $r = 0.76$ to 1.0 respectively [43]. Direct observation was selected as the primary outcome as direct observational methods provide a more precise account of behaviour defined by the researcher and not the parent [44]. Additionally, this observational measure has been used in a number of previous studies at the centre [10, 38, 45].

There are eight DPICS parent categories summarised in terms of positive and negative parenting. Positive parenting categories comprise of direct command, labelled praise, unlabelled praise and descriptive commenting/verbal labelling. Negative parenting categories comprise of indirect command, questions, critical statement and negative command. No child categories will be recorded; child behaviour will be measured using the parent report ECBI only, as the main purpose of this study is to see whether the intervention has an affect on parental behaviour. Observational coding is continuous and records the total frequency of each category of parent behaviour for a total of thirty minutes. Inter-rater levels of reliability will be assessed for 20% of all observations at all three-time points.

Secondary outcomes

The following secondary outcomes will be collected at the three time points by the research team for the intervention group and twice for the wait-list control group.

- Child behaviour as measured by the Eyberg Child Behaviour Inventory [1]. This measure is a 36-item inventory completed by the parent to assess the frequency and intensity of child behavioural problems for children aged 2-16 years, and has been used in many previous trials including several that have been conducted at the centre [10, 37]. Factor analyses of the ECBI for both children and adolescents indicate that it is a uni-dimensional measure of conduct problem behaviours [36].
- Parenting practices as measured by the Arnold O'Leary Parenting Scale [46]. This is a 30-item inventory with three subscales measuring parental behaviour: laxness, over-reactivity and verbosity. Responses are recorded on a seven-point scale with two alternative responses to a particular parental situation. The parenting scale has been shown to exhibit adequate internal validity and test-retest reliability [46] in addition to

demonstrating significant correlations with observational measures of child problem behaviour [46].

- Parental confidence as measured by the Parental Sense of Competence questionnaire [47]. This 17-item likert–scale questionnaire measures competence on two separate dimensions: satisfaction and efficacy. The satisfaction questions measure parental anxiety, motivation and frustration (for example, 'sometimes I feel like I'm not getting anything done') and the efficacy question examine competence, capability levels and problem-solving skills (for example, 'I meet my own personal expectations for expertise in caring for my child') in relation to parenting [47]. Ohan, Leung and Johnston [48] replicated the factor structure of the Parenting Sense of Competence Scale produced by Johnston and Mash [47], and provided evidence that the satisfaction and efficacy scales from this measure assess distinct aspects of parenting self-esteem.
- Parental mental health as measured by the General Health Questionnaire [49]. This is a 30-item questionnaire and each item invites one of four responses in order to assess psychiatric symptoms including social dysfunction, sleeping patterns and depression [50]. The responses include 'better than usual', 'same as usual', 'less than usual' and 'much less than usual' to questions such as 'have you found everything getting on top of you?' and 'have you been getting edgy and bad tempered?' This measure was used as research has demonstrated the association between maternal mental health and child conduct problems [51]. Reliability coefficients of the questionnaire have ranged from 0.78 to 0.95 in various studies [52]. There have been several factor analyses of the GHQ-30 in relatively large community samples [50].

Demographic information

Demographic information will be collected from all participants at baseline prior to randomisation. The demographic questionnaire is based on the 'Personal Development and Health Questionnaire' [53] and will include data on socioeconomic status, including poverty, parental educational level and single-parent status. The questionnaire will cover the following information:

- Age of parent and child, gender of parent and child, child diagnosis, parent's relationship to the child (biological or non-biological parent), parent's age at birth of first child, how many children the parent has, ages of all children, parent's current relationship status, partner's relationship to the child, housing situation, employment status, income, parent's level of education and whether they have previously attended a parenting course. An additional question regarding their internet usage is also included.

Data Collection

Members of the research team will collect parental self-report measures and observational data on parent-child interaction using the DPICS behaviour coding system, during home visits at baseline and follow-up. There is a possibility that parents will drop out of the programme before the end; nonetheless all efforts will be made to collect follow-up data. Parents will also be asked to complete a short feedback/satisfaction questionnaire at the end of the study to share their views of the programme.

The DPICS has been used in a number of studies evaluating parenting programmes [10, 46, 52]. Research team members are already trained in DPICS coding and have reached 80% inter-rater reliability across all categories. At least two coders, to establish inter-rater

reliability, will code 20% of observations at each time-point simultaneously (baseline and follow-up). Frequent practice sessions and meetings will be held to discuss any matters arising and to ensure maintenance of a minimum level of 80% reliability.

Sample Size

The intention is to enroll 60 parents (40 to intervention and 20 to wait-list control, randomised on a 2:1 ratio). Due to limited funds and time restrictions associated with recruitment and data collection, a larger sample size would be difficult to recruit within the time frame. However, this is a pilot RCT study and is exploratory in nature; and a sample size of 60 parents should be sufficient to explore initial outcomes in terms of encouragement in the use of positive parental strategies.

Randomisation

Once all of the data for individual parents have been collected at baseline, parents will be randomised to either the intervention or a wait-list control condition on a 2:1 ratio. This allows for the evaluation of a larger intervention sample whilst also reducing the number of parents waiting for the intervention. This design is favoured for research in this field [10]. A control condition was favoured over an alternative treatment condition as the researchers wanted to ensure that all participants received access to the intervention. The randomisation will be stratified according to child age (3-5 and 6-8 years old) and gender (male and female) using the online software 'sealed envelope'. The centre administrative assistant will undertake the randomisation process, which will require entering the participant identification number, child age and child gender. The software will then generate the decision on whether the participant has been allocated to the intervention (group 1) or control (group 2) condition. Parents will receive a letter from the administrator informing them of their group allocation

and intervention parents will receive the link to the website and their log in details with this letter. Control parents will be informed that they will receive their log in details upon completion of the second home visit (post-intervention data).

(Insert Figure 1 here)

Blinding

Baseline measures will be completed prior to randomisation and parents will be asked (during home visits) not to reveal their group allocation to researchers in order, as far as possible, to keep the researchers blind to parent group allocation. However, some parents may reveal their allocation during the first follow-up home visits. In this instance, researchers will make a record of this. Due to the design of the study, it will not be possible to keep the researchers blind to group allocation at the second six-month follow-up stage as they will only involve intervention parents. However the key measures are parent report questionnaires and the frequency based behavioural observation that incorporates inter-rater reliability. If high levels of unmasking occur, a variable will be added to the analysis to control for this.

Statistical Analysis

Baseline characteristics for all parents and children will be analysed and checked for differences (if any) between the intervention and wait-list control groups. Any differences will be recorded and accounted for the in the analysis. ANCOVA will be used as the main analysis method to compare the intervention and wait-list control groups. Any missing data will be treated using multiple imputation, a relatively flexible, general-purpose approach to dealing with missing data [54].

Discussion

This trial will provide information on the effectiveness of an online parenting programme, an intervention designed to increase positive parenting for parents of children aged 3-8 years. The effects of the intervention on child behaviour, parenting behaviour, parental mental health and parental sense of competence will also be assessed. This project is timely when considering the current situation with regards to rising numbers of children displaying behaviour problems [4] and the known impact of parenting style on the establishment and maintenance child behaviour problems [52, 12, 35]. Additionally, this online programme targets intervention barriers, as parents can complete the web-based programme at home at a convenient time without relying on referrals from professionals.

This intervention has the potential to be a cost-effective early intervention prevention resource both for parents for whom no support would otherwise be available and/or as an alternative cost effective resource for use by the health care services [55]. An evidence-based online intervention could allow professionals to spend more time and resources supporting families with more significant problems, by enabling parents who require general parenting support to access a web-based programme. This could potentially reduce the number of families seeking advice for whom no service currently exists [19].

Proposed results

This evaluation of a web version of a parenting programme based on 'The Little Parent Handbook', which itself includes material developed as part of an evidence-based intervention, should be a useful addition to the parenting literature. Both parents recruited to the trial and healthcare professionals will be notified of the results of the trial by means of a letter. Researchers will also verbally present the findings to healthcare professionals. If

significant benefits are found, the intervention could be made available for health visitors and school nurses to distribute to parents on a regular basis, although there are no plans for wider dissemination at this current stage due to cost implications. It is hypothesised that the online programme will encourage parents to use positive parenting strategies, including spending more time with their child and praising and rewarding positive child behaviour. Additionally, it is hypothesised that the online programme will improve a range of outcomes including self-reported parenting practices, parental mental health, parental confidence and child behaviour.

Trial status

The trial is currently on going. Baseline measures for all parents were completed in July 2016 and 3 month-follow up visits are due to be completed by October 2016.

Abbreviations

NICE: The National Institute for Health and Care Excellence; ONS: Office for National Statistics, ANCOVA; Analysis of Covariance; REC: Research Ethics Committee

Author's contributions

DAO: designing of the online programme, manuscript writing, gaining ethical approval, data collection, data analysis, critical revision and final approval of manuscript. NG: critical revision and final approval of manuscript. JH: author of 'The Little Parent Handbook', critical revision and final approval of manuscript.

Competing interests: The third author [JH] is the author of 'The Little Parent Handbook.

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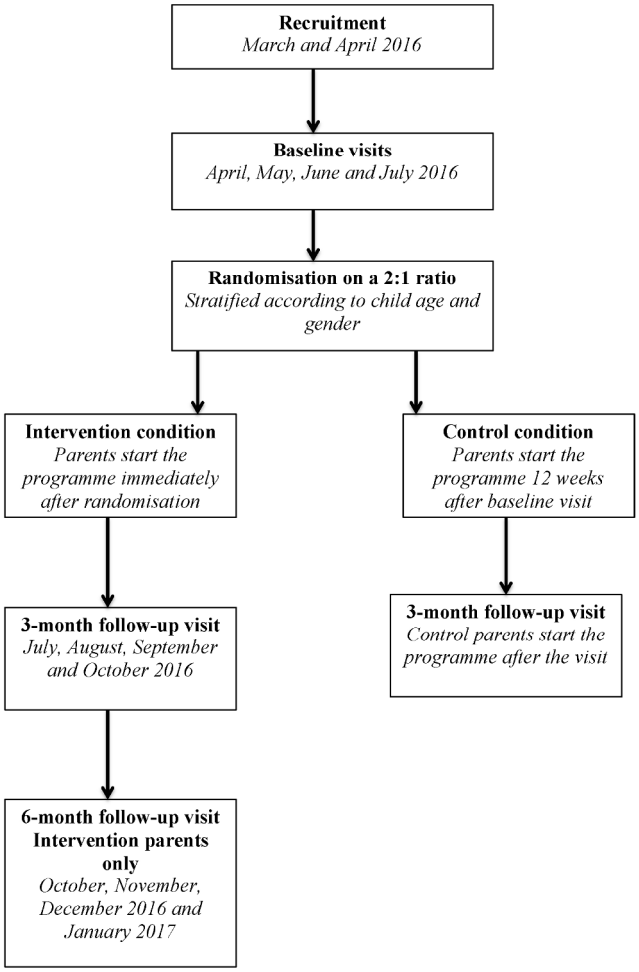
Figure legend: Participant flow chart



Participant flow chart

209x297mm (300 x 300 DPI)

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description
Administrative information		
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym **(page 1)**
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry **(page 3)**
	2b	All items from the World Health Organization Trial Registration Data Set **(not applicable)**
Protocol version	3	Date and version identifier **(page 1)**
Funding	4	Sources and types of financial, material, and other support **(page 1)**
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors **(page 1)**
	5b	Name and contact information for the trial sponsor **(page 1)**
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities **(page 22)**
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) **(not applicable – all work carried out by the authors)**
Introduction		
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention **(pages 3 – 7)**
	6b	Explanation for choice of comparators **(page 19)**
Objectives	7	Specific objectives or hypotheses **(pages 7–8)**

Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) **(page 8)**
Methods: Participants, interventions, and outcomes		
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained **(page 8)**
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) **(page 9)**
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered **(pages 10–15)**
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) **(no criteria for discontinuing treatment)**
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) **Not applicable**
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial **Not applicable**
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended **(pages 15-18)**
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) **(insert figure on page 20)**
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations **(page 19)**
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size **(pages 9-10)**
Methods: Assignment of interventions (for controlled trials)		
Allocation:		

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions **(pages 19-20)**
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned **(pages 19-20)**
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions **(pages 19-20)**
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how **(page 20)**
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial **(page 20)**
Methods: Data collection, management, and analysis		
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol **(pages 18-19)**
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols **(page 18)**
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol **(pages 18-19)**
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol **(page 20)**
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses) **(page 20)**
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) **(page 20)**

Methods: Monitoring

Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed **Not applicable**
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial **Not applicable**
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct **Not applicable**
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor **(process will not be independent from Bangor University)**

Ethics and dissemination

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval **(pages 2-3)**
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators) **(authors will contact relevant parties if any changes to protocol should occur)**
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) **(pages 9-10)**
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable **Not applicable**
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial **(all data will remain confidential before, during and after the trial)**
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site **(page 22)**
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators **(only the authors will have access to the data)**

Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation **Not applicable**
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions **(pages 21-22)**
	31b	Authorship eligibility guidelines and any intended use of professional writers **Not applicable**
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code **No plans**
Appendices		
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates **Uploaded with submission**
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable **Not applicable**

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

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Evaluation of an online parenting programme based on 'The Little Parent Handbook': Study protocol for a pilot randomised controlled trial

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Title: Evaluation of an online parenting programme based on 'The Little Parent Handbook': Study protocol for a pilot randomised controlled trial

Authors: Dawn Adele Owen, Nia Griffith, Judy Hutchings

Author details:

Centre for Evidence Based Early Intervention, School of Psychology, Nantlle Building, Normal Site, Bangor University, Bangor, Gwynedd, LL57 2PZ, UK (01248 383 758).

Email: dawn.a.owen@bangor.a.uk

School of Psychology, Wheldon Building, Room 113, Bangor University, Bangor, Gwynedd, LL57 2PZ, UK.

Email: n.griffith@bangor.ac.uk

Centre for Evidence Based Early Intervention, School of Psychology, Nantlle Building, Normal Site, Bangor University, Bangor, Gwynedd, LL57 2PZ, UK.

Email: j.hutchings@bangor.ac.uk

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Abstract

Introduction: The online parenting programme based on 'The Little Parent Handbook' is a web-based parenting intervention for parents of children aged 3-8 with an interest in positive parenting. The programme focuses on strengthening parent-child relationships through encouraging positive child behaviour. This trial will evaluate whether the intervention is effective in increasing the use of positive parenting strategies outlined in the programme using parent report and blind observation.

Methods and analysis: This is a pilot randomised controlled trial with intervention and wait-list control conditions. The intervention is a ten-week online parenting programme to promote positive parent-child relations by teaching core social learning theory principles that encourage positive child behaviour, primarily through the use of praise and rewards. Health visitors and school nurses will circulate a recruitment poster to parents of children aged 3-8 years on their current caseloads. Recruitment posters will also be distributed via local primary schools and nurseries. Parents recruited to the trial will be randomised on a 2:1 ratio to intervention or wait-list control conditions (stratified according to child gender and age). The primary outcome measure is positive parenting as measured by a behavioural observation of parent-child interactions using the Dyadic Parent-Child Interaction Coding System [1]. Secondary outcomes include parental report measures of child behaviour, self-reported parental sense of competence, parenting behaviour and parental mental health. Data will be collected at baseline and three months later (post-intervention) for all participants and six months post-baseline for the intervention group only. ANCOVA will be the main statistical method used.

Ethics and dissemination: The trial has received ethical approval from the NHS Betsi Cadwaladr University Health Board Ethics Committee (REC) and the School of Psychology,

Bangor University REC (15/WA/0463). Publications of all outcomes will be in peer-reviewed journals and conference presentations.

Trial registration: Current Controlled Trials ISRCTN89370147 (May 5th 2016).

Strengths and limitations

- This is a randomised Controlled Trial with a wait-list control group.
- The behavioural observations incorporate inter-rater reliability (20% of all observations at the separate time points).
- Once randomised, intervention parents start the online programme immediately thus reducing the amount of time spent waiting for the intervention.
- A limitation of this study is parents are required to log in each week and engage with the programme, this may result in some parents not fully engaging and the potential loss of follow-up data.
- Due to time and funding constraints, this trial aims to enroll sixty parents, which is a fairly small sample size.
- Funding and time constraints do not allow for a longer-term follow-up.

Background

Minor child problem behaviours can develop into more significant problems unless addressed while children are still young [2] and there are high costs associated with child mental health and behavioural problems [3]. Conduct problems have a significant impact on children's functioning and quality of life [4] with up to 50% of children and young people with conduct disorder developing antisocial personality disorder [5, 4]. This highlights the importance of providing early universal support to parents to avoid the small behavioural challenges faced by all parents from progressing into more costly ones.

Children who are at risk of poor outcomes, including impairments in social, emotional and educational functioning [6], often experience harsh and inconsistent parenting from parents who show little positive parental involvement [7]. Problematic parenting strategies can be addressed through teaching positive parenting skills to target such child behaviour problems and achieve positive outcomes [8, 9, 10, 11]. These positive parenting skills that are associated with positive child outcomes are well established and include play, praise, reward, and positive affect [8].

A successful intervention for parents of children with significant behavioural difficulties [10] used mediator analysis to demonstrate that the mechanism for change in child behaviour was change in parental behaviour [12]. Similarly, teaching positive parental strategies has been shown to increase positive parenting style as measured by direct observation of parent-child interactions [13]. Whilst these studies have focused on programmes for parents of children with, or at risk of, significant problems, there is less evidence for the benefits of parenting programmes for parents in general. Public policy recognises the need for early intervention and support for families, but it is not universally available and remains "patchy" [14].

In the UK, the National Institute for Health and Care Excellence [4] identified the Incredible Years Parent Programme as a treatment for conduct disorder [15], and this evidence-based programme was introduced to North West Wales through the NHS Child and Adolescent Mental Health Service in the 1990s (CAMHS) [15]. Numerous Randomised Controlled Trials have shown significant improvements for child behaviour following the intervention [10, 16]. However, these programmes are not readily available. The Flying Start initiative offers parenting programmes on an annual basis to families living in disadvantages areas with a child aged four years or younger [17], and may not be accessible to some families due to barriers [18] for example, the inconvenience of travel to the clinical setting or organising

childcare arrangements for groups scheduled during weekday hours can be particularly burdensome [19]. Additionally, these programmes can be costly as an effective analysis of the Incredible Years basic parenting programme showed that the intervention improved children's behaviour at a cost of £1344 per child [20].

Challenges in the availability of parenting programmes has resulted in health visitors and school nurses supporting the majority of families in the UK with children at significant risk of poor outcomes, reducing their ability to provide adequate support to all families. A survey of health visitors and school nurses reported that 53% of health visitors saw between 21-50, and 46% of school nurses saw between 50-99 children with emotional or behavioural problems each week [21]. A review of parental and professional perceptions of barriers to parenting interventions [18] highlighted five challenges for both parents and facilitators; (1) situational barriers, (2) psychological barriers including fear of being criticised or stigmatised [22], (3) lack of information/misconception about services, (4) availability of services and (5) poor interagency collaboration. These barriers suggest there could be benefits from alternative modes of programme delivery including behavioural interventions delivered online [23].

Technology has the potential to enhance parental engagement, teach key parenting skills, reduce the cost burden associated with group and one-to-one interventions, alleviate pressures on services, particularly those delivered by heath visitors and school nurses, and offer more flexible access [23, 24, 25]. Access to technology is now feasible for many parents due to increased availability of internet access [26]. The number of households with computers increased from 8% to 60% between 1984 and 2003 in the US, and in the UK by 2015, 86% of households had internet access [27]. The majority of parents (75%) now use

social media to obtain parent-related information [28] with over eight million people visiting an online parenting information and advice website every month [29].

Although as yet limited in number, web-based programmes for behaviour change (including weight loss and alcohol reduction) have achieved positive outcomes [30, 31], suggesting that technology can be an effective means of providing behaviour change advice and support. Similarly, there is evidence demonstrating increased positive parenting following web-based interventions [32, 33]. Parents of children aged between 3-12 years with conduct disorder who accessed an online parenting programme, reported less use of harsh parenting and more use of positive praise compared to wait-list control parents [33], and these findings were maintained at the six-month follow-up. However, evidence in this field is currently limited and universal programmes need more evidence to demonstrate effectiveness with families who are not necessarily experiencing significant levels of child problem behaviours. Bayer and colleagues highlighted the importance of offering parental support universally (1) so as not to stigmatise at-risk populations and (2) to prevent missing early signs of problems for families not classified as at-risk [34].

Web based interventions allow parents to access support at home at a time most convenient for their individual family circumstances, eliminating one of the barriers associated with more traditional intervention approaches. The internet allows access to advice without having to seek referral or further advice from health care professionals. This could allow professionals, such as health visitors and school nurses, more time and resources to target clinical (or identified at-risk) populations with more individualised interventions. Providing parents access to online advice and support could increase parental understanding of how to promote positive child development and potentially prevent the development of child

behaviour problems. Providing positive parenting support in general could avoid the intergenerational transfer of poor parenting practices [14].

Rationale

The aim of the web based parenting programme, based on 'The Little Parent Handbook' [35], is to provide information and activities based on core social learning theory principles associated with positive parenting practices and good child outcomes to parents of children aged 3-8 years. The study will explore the delivery of the programme, parental satisfaction and engagement with the programme and whether it is effective in demonstrating increased use of positive parental practices in parents of children with a wide age range and varying behavioural patterns.

Aims and Objectives

The aim of this trial is to conduct a pilot randomised controlled trial (RCT) on the effectiveness of an online parenting programme, for parents of children aged 3-8 years who would like to learn more about positive parenting by comparing outcomes for intervention and wait-list control groups.

The key objectives are to establish whether the programmes successfully engages and retains parents; whether the programme produces statistically significant increases in positive parenting as observed in a parent-child observation when compared to wait-list control parents; and to determine whether the online programme produces any changes in secondary outcomes (parent-reported child behaviour, parent self-reported sense of competence, behaviour and mental health). The study hypotheses are:

i. the online parenting programme will lead to significant increases in positive parenting strategies as displayed in the behavioural observation coded using Dyadic Parent-Child Interaction Coding System [1]

ii. the online programme will significantly increase positive behaviours and mental health of parents, including self-reported parenting skills, parental sense of competence and parental mental health

iii. the online programme will lead to reduction in parent-reported levels of child problem behaviour as reported using the Eyberg Child Behaviour Inventory [36]

Methods/Design

Trial design

This pilot RCT will explore the effectiveness of an online parenting programme. Parents of children aged 3-8 years who would like to learn more about positive parenting will be randomly allocated to the intervention condition with immediate access to the programme or to a 3-month wait-list control group on a 2:1 ratio. Self-report and observational data will be collected in parents' homes during home visits and parents will access the programme at home.

Eligibility criteria

To be eligible for the study parents must have a child aged between 3-8 years, be able to understand English (as the programme is only currently available in English) and be able to access the internet on a PC, laptop, iPad or tablet. The software does not yet support smartphones. Parents who are currently receiving support from services are also invited to participate (they will be asked to record which services they are receiving and the duration).

Individuals will be excluded from the study if a parents does not have a child aged between 3-8 years, does not understand English and does not have access to the internet.

Recruitment

Health visitors and school nurses in Gwynedd and Anglesey (North-West Wales) will approach parents of children aged 3-8 years on their own caseloads and describe the online programme and the research trial. If parents decide that they might want to sign up for the study, they will be asked by the health visitor/school nurse to complete a note of interest form, that will be sent to the research office at Bangor University, giving consent for a member of the research team to contact the parent.

On receipt of the note of interest form, a member of the research team will contact the parent to arrange a convenient time to visit and discuss the project further. The researcher will go through the information sheet with the parent during this home visit and ensure that any questions are answered. If the parent is happy to continue, the researcher will obtain informed consent from the parent to participate in the study. Only when consent has been obtained will the researcher proceed to ask the parent to fill out the self-report measures and take part in a 30-minute behavioural observation of parent-child interaction.

In addition to health visitors and school nurses approaching parents on their caseloads, recruitment posters will be distributed in primary schools and nurseries in Gwynedd, Anglesey, Conwy and Denbighshire. An e-mail address and a contact telephone number will be provided on the recruitment poster so that interested parents can contact the research team directly. Parents will either be sent a detailed information sheet via e-mail or the researcher will discuss the research in depth over the telephone. If parents would still like to participate,

arrangements will then be made for a home visit to discuss the study further. Similarly, parents who hear about the study through word of mouth can contact the research team for further information regarding the trial.

It is expected that both forms of recruitment (poster and health visitor/ school nurse) will attract parents from varying socioeconomic backgrounds who are experiencing varying levels of child problem behaviour. For the purpose of this pilot trial, baseline characteristics of all parents will be reported and compared with the population as a whole. Additionally, the percentage of parents recruited from each source will be reported and their characteristics compared in order to explore the effects of the intervention for the whole sample.

Intervention

Trials conducted by Hutchings and colleagues during the 1990s [37, 38] with parents and health visitors demonstrated positive outcomes from teaching effective behavioural strategies to parents of children with challenging behavior for both clinically referred and pre-school prevention populations. Significant overall improvements were found for intervention families on measures of child behaviour, parenting practices and maternal mental health [37, 39]. As part of these trials intervention parents were provided with help sheets that were subsequently published as 'The Little Parent Handbook' [35]. These trials were multi-component trials and so it is difficult to establish the true extent of the effectiveness of the parent help-sheets, however they contained the evidence based behavioural principles on which the interventions were based.

The LifeGuide software, developed at the University of Southampton [40], was used in the creation of the online parenting programme. The aim of LifeGuide is to continuously

develop, evaluate and disseminate a set of tools that will allow researchers to flexibly create and modify online behaviour change interventions [41]. LifeGuide software allows researchers to deliver behavioural principles both through programme delivery (text message prompts etc.) and programme content (The Little Parent Handbook).

Features of the online parenting programme include automated feedback based on individual performance, online praise messages for spending time with their child, text message reminders to access the next session, and multiple-choice quizzes to test knowledge. The programme also enables the tracking of individual usage data (which can be extracted into Microsoft Excel), including the number of log in, time spent on each page and the number of chapters completed.

The programme introduces evidence-based behavioural principles that have been shown to be effective in strengthening parent-child relations through encouraging positive child behaviour [42]. A small-scale feasibility study of the online parenting programme was conducted at the end of 2015 with the aim of providing user feedback prior to conducting this larger-scale RCT trial. This study had no measures and participants were not randomised, instead twenty participants were asked to complete the intervention and fill out a feedback form. Overall, feedback was very positive with the majority of participants reporting that they would recommend the programme to parents of children aged 3-8 years. Minor modifications were made based on the feedback, these include text message prompting parents to log-in to subsequent sessions, more video examples of positive parenting and the option to look back over previously completed chapters again. The intervention consists of ten chapters, eight content and two revision chapters. The topics are:

i. Spending special time with your child through play

ii. Encouraging good behaviour through praising

iii. Encouraging good behaviour through rewarding

iv. How to get better at giving instructions [part 1]

v. How to get better at giving instructions [part 2]

vi. Revision

vii. Ignoring problem behaviour

viii. Teaching your child new behaviours

ix. How to develop your child's language skills

x. Revision

Intervention parents will be provided with a link to the website and a username and password. Contact details of an administrator will be provided in case any parent requires technical support during the programme. Parents will be asked to log in and complete one chapter each week, each chapter will take approximately thirty minutes to complete. The software ensures that parents have completed each chapter before they can move on to the next one; they are not required to complete the chapter in one sitting. Log in details allow parents to access the programme as many times as they wish. The intervention has been programmed to take parents to the last page that they viewed on the next occasion that they log in to avoid parents having to start the programme from the beginning. In order to give parents sufficient time to practice the principles outlined in the individual chapters, the intervention has been programmed so that there will be a minimum five-day gap between each chapter. If parents log in before the five days have elapsed, they will be offered the opportunity to look back over previously completed chapters again.

The programme asks parents to practice the skills presented in the chapter with their child at home. Each chapter concludes with a suggested practice activity. Parents are also encouraged

to keep paper records detailing their activities. Parents can also record online each week how many times they have played with their child by selecting the amount of times from a drop-down menu. The programme encourages parents to spend more time playing with their child in order to strengthen their relationship, and they are continuously reminded to engage in this activity throughout the programme both by praise messages and by being prompted to record the amount of time spent playing. A praise message congratulates the parent for spending time with their child if they report spending time with their child during the past week, or since the last time they logged in. If parents do not report having spent time with their child during the past week, a prompt message appears reminding them of the importance of this activity.

Each chapter covers an individual behavioural principle that aims to strengthen the parent-child relationship. Parents read through information (or listen via an audio button if they prefer) and watch video examples of positive parenting. The video clips are short in length (all are less than one minute long) allowing the opportunity for multiple viewing. At the end of each chapter there is a longer video and parents are asked to answer three questions based on the video clip (by selecting yes or no) in order to develop their observational skills and to encourage them to identify positive child behaviours. For example, at the end of chapter two (praising positive behaviour) parents are prompted to watch a video of a parent giving her child a specific labelled praise, and then answering three questions based on the video; (1) Did the parent praise the child immediately? (2) Was the parent close to the child when praising? (3) Did the parent share positive feelings when praising? A score out of three and the correct answers are provided for the responses to the videos.

Each chapter ends with a multiple-choice quiz to test parents' knowledge and understanding of key principles. Parents will be given online automated feedback on their quiz scores in addition to the correct answers. Parents also have an option to download and print a summary sheet for each chapter.

Parents will be given an opportunity to receive text message prompts to help keep them on track. If they would like to receive text messages, they will be asked at the beginning of the programme to enter their mobile phone number. The programme is fully automated, and the research team will have no contact with parents during the intervention. The centre administrator can be contacted if parents require any technical assistance during the study. A text message will be sent five days after the completion of a chapter informing the parent that the next chapter is now available. If the parent has not logged into the programme to complete the next chapter three days after it becomes available, a reminder text will be sent prompting them to log in and complete the next chapter. If a parent still has not logged in, weekly reminders will be sent. LifeGuide does not allow researchers to track how many messages parents have received, however, researchers will calculate the number of text messages each participant has received depending on the programme schedule, e.g. if a parent has not logged on after three days of the chapter becoming available they will have received one text message, etc. Therefore it will be possible to monitor the level of prompting each participant receives.

Baseline data will be collected prior to randomisation and, once it is completed, intervention parents will receive a notification of their status and their log in details, whilst parents in the wait-list control group will be informed that they will have access to the programme after three months. Follow up data will be collected after three moths regardless of whether

intervention parents have completed the programme. Once post-intervention data has been collected, control group parents will receive their log in details for the programme. On completion of both baseline and follow-up visits, families will receive a children's book as a thank you for their time. On completion of all measures, all parents will receive a copy of 'The Little Parent Handbook'. Data collection will begin in April 2016 and end in February 2017.

Primary measure

The primary outcome is to establish whether the online parenting programme produces significant changes in positive parenting practices from baseline to follow-up as recorded using the DPICS. The researcher will observe the parent and child engaging in child-led play for thirty minutes. This coding system was specifically designed to assess the quality of parent-child social interaction [43]. The DPICS has demonstrated high inter-rater reliability for parent and child behaviours, $r = 0.67$ to 1.0 and $r = 0.76$ to 1.0 respectively [43]. Direct observation was selected as the primary outcome as direct observational methods provide a more precise account of behaviour defined by the researcher and not the parent [44]. Additionally, this observational measure has been used in a number of previous studies at the centre [10, 38, 45].

There are eight DPICS parent categories summarised in terms of positive and negative parenting. Positive parenting categories comprise of direct command, labelled praise, unlabelled praise and descriptive commenting/verbal labelling. Negative parenting categories comprise of indirect command, questions, critical statement and negative command. No child categories will be recorded; child behaviour will be measured using the parent report ECBI only, as the main purpose of this study is to see whether the intervention has an affect on

parental behaviour. Observational coding is continuous and records the total frequency of each category of parent behaviour for a total of thirty minutes. Inter-rater levels of reliability will be assessed for 20% of all observations at all three-time points.

Secondary measures

The following secondary outcomes will be collected at the three time points by the research team for the intervention group and twice for the wait-list control group.

- Child behaviour as measured by the Eyberg Child Behaviour Inventory [1]. This measure is a 36-item inventory completed by the parent to assess the frequency and intensity of child behavioural problems for children aged 2-16 years, and has been used in many previous trials including several that have been conducted at the centre [10, 37]. Factor analyses of the ECBI for both children and adolescents indicate that it is a uni-dimensional measure of conduct problem behaviours [36].
- Parenting practices as measured by the Arnold O'Leary Parenting Scale [46]. This is a 30-item inventory with three subscales measuring parental behaviour: laxness, over-reactivity and verbosity. Responses are recorded on a seven-point scale with two alternative responses to a particular parental situation. The parenting scale has been shown to exhibit adequate internal validity and test-retest reliability [46] in addition to demonstrating significant correlations with observational measures of child problem behaviour [46].
- Parental confidence as measured by the Parental Sense of Competence questionnaire [47]. This 17-item likert–scale questionnaire measures competence on two separate dimensions: satisfaction and efficacy. The satisfaction questions measure parental anxiety, motivation and frustration (for example, 'sometimes I feel like I'm not getting anything done') and the efficacy question examine competence, capability

levels and problem-solving skills (for example, 'I meet my own personal expectations for expertise in caring for my child') in relation to parenting [47]. Ohan, Leung and Johnston [48] replicated the factor structure of the Parenting Sense of Competence Scale produced by Johnston and Mash [47], and provided evidence that the satisfaction and efficacy scales from this measure assess distinct aspects of parenting self-esteem.

- Parental mental health as measured by the General Health Questionnaire [49]. This is a 30-item questionnaire and each item invites one of four responses in order to assess psychiatric symptoms including social dysfunction, sleeping patterns and depression [50]. The responses include 'better than usual', 'same as usual', 'less than usual' and 'much less than usual' to questions such as 'have you found everything getting on top of you?' and 'have you been getting edgy and bad tempered?' This measure was used as research has demonstrated the association between maternal mental health and child conduct problems [51]. Reliability coefficients of the questionnaire have ranged from 0.78 to 0.95 in various studies [52]. There have been several factor analyses of the GHQ-30 in relatively large community samples [50].

Demographic information

Demographic information will be collected from all participants at baseline prior to randomisation. The demographic questionnaire is based on the 'Personal Development and Health Questionnaire' [53] and will include data on socioeconomic status, including poverty, parental educational level and single-parent status. The questionnaire will cover the following information:

- Age of parent and child, gender of parent and child, child diagnosis, parent's relationship to the child (biological or non-biological parent), parent's age at birth of first child, how many children the parent has, ages of all children, parent's current relationship status, partner's relationship to the child, housing situation, employment status, income, parent's level of education and whether they have previously attended a parenting course. An additional question regarding their internet usage is also included.

Data Collection

Members of the research team will collect parental self-report measures and observational data on parent-child interaction using the DPICS behaviour coding system, during home visits at baseline and follow-up. There is a possibility that parents will drop out of the programme before the end; nonetheless all efforts will be made to collect follow-up data. Parents will also be asked to complete a short feedback/satisfaction questionnaire at the end of the study to share their views of the programme.

The DPICS has been used in a number of studies evaluating parenting programmes [10, 46, 52]. Research team members are already trained in DPICS coding and have reached 80% inter-rater reliability across all categories. At least two coders, to establish inter-rater reliability, will code 20% of observations at each time-point simultaneously (baseline and follow-up). Frequent practice sessions and meetings will be held to discuss any matters arising and to ensure maintenance of a minimum level of 80% reliability.

Sample Size

The intention is to enroll 60 parents o children aged 3-8 years (40 to intervention and 20 to wait-list control, randomised on a 2:1 ratio). Due to limited funds and time restrictions associated with recruitment and data collection, a larger sample size would be difficult to recruit within the time frame. Additionally, this is a pilot RCT with the aim of exploring initial outcomes (in terms of measures, delivery and acceptance of the programme) with a view to conducting a larger scale trial in the future. Results from this pilot trial will give researchers initial information regarding acceptability and delivery of the programme with parents of children aged 3-8 years and should be sufficient to explore initial outcomes in terms of encouragement in the use of positive parental strategies that would inform a power calculation for a larger definitive study.

Randomisation

Once all of the data for individual parents have been collected at baseline, parents will be randomised to either the intervention or a wait-list control condition on a 2:1 ratio. This allows for the evaluation of a larger intervention sample whilst also reducing the number of parents waiting for the intervention. This design is favoured for research in this field [10]. A control condition was favoured over an alternative treatment condition as the researchers wanted to ensure that all participants received access to the intervention. The randomisation will be stratified according to child age (3-5 and 6-8 years old) and gender (male and female) using the online software 'sealed envelope'. The centre administrative assistant will undertake the randomisation process, which will require entering the participant identification number, child age and child gender. The software will then generate the decision on whether the participant has been allocated to the intervention (group 1) or control (group 2) condition. Parents will receive a letter from the administrator informing them of their group allocation and intervention parents will receive the link to the website and their log in details with this

letter. Control parents will be informed that they will receive their log in details upon completion of the second home visit (post-intervention data).

(Insert Figure 1 here)

Blinding

Baseline measures will be completed prior to randomisation and parents will be asked (during home visits) not to reveal their group allocation to researchers in order, as far as possible, to keep the researchers blind to parent group allocation. However, some parents may reveal their allocation during the first follow-up home visits. In this instance, researchers will make a record of this. Due to the design of the study, it will not be possible to keep the researchers blind to group allocation at the second six-month follow-up stage as they will only involve intervention parents. However the key measures are parent report questionnaires and the frequency based behavioural observation that incorporates inter-rater reliability. If high levels of unmasking occur, a variable will be added to the analysis to control for this.

Statistical Analysis

Baseline characteristics for all parents and children will be analysed and checked for differences (if any) between the intervention and wait-list control groups. Any differences will be recorded and accounted for the in the analysis. ANCOVA will be used as the main analysis method to compare the intervention and wait-list control groups. Any missing data will be treated using multiple imputation, a relatively flexible, general-purpose approach to dealing with missing data [54].

Discussion

This trial will provide information on the effectiveness of an online parenting programme, an intervention designed to increase positive parenting for parents of children aged 3-8 years. The effects of the intervention on child behaviour, parenting behaviour, parental mental health and parental sense of competence will also be assessed. This project is timely when considering the current situation with regards to rising numbers of children displaying behaviour problems [4] and the known impact of parenting style on the establishment and maintenance child behaviour problems [52, 12, 35]. Additionally, this online programme targets intervention barriers, as parents can complete the web-based programme at home at a convenient time without relying on referrals from professionals.

This intervention has the potential to be a cost-effective early intervention prevention resource both for parents for whom no support would otherwise be available and/or as an alternative cost effective resource for use by the health care services [55]. An evidence-based online intervention could allow professionals to spend more time and resources supporting families with more significant problems, by enabling parents who require general parenting support to access a web-based programme. This could potentially reduce the number of families seeking advice for whom no service currently exists [19].

Proposed results

This evaluation of a web version of a parenting programme based on 'The Little Parent Handbook', which itself includes material developed as part of an evidence-based intervention, should be a useful addition to the parenting literature. Both parents recruited to the trial and healthcare professionals who were involved in the recruitment phase will be notified of the results of the trial by means of a letter. Researchers will also verbally present

the findings to healthcare professionals. If the trial suggests that there are significant benefits, this would inform a bid for funds for a larger definitive RCT with the goal that the intervention could subsequently be made available to parents in general as a preventative programme. This programme could potentially be useful to parents who would like to receive additional support, but who are not living in targeted areas (such as Flying Start areas in Wales) where higher levels of parenting support are provided. A preventative universal programme available to all parents could potentially allow health care professionals more time and resources to target clinical (or at-risk) populations and also encourage parents to use well established positive parenting strategies to prevent child behaviour problems from forming. A universal preventative programme such as this could be useful in encouraging positive parenting practices for all parents.

It is hypothesised that the online programme will encourage parents to use positive parenting strategies, including spending more time with their child and praising and rewarding positive child behaviour. Additionally, it is hypothesised that the online programme will improve a range of outcomes including self-reported parenting practices, parental mental health, parental confidence and child behaviour.

Trial status

The trial is currently on going. Baseline measures for all parents were completed in July 2016 and 3 month-follow up visits are due to be completed by October 2016.

Abbreviations

NICE: The National Institute for Health and Care Excellence; ONS: Office for National Statistics, ANCOVA; Analysis of Covariance; REC: Research Ethics Committee

Author's contributions

DAO: designing of the online programme, manuscript writing, gaining ethical approval, data collection, data analysis, critical revision and final approval of manuscript. NG: critical revision and final approval of manuscript. JH: author of 'The Little Parent Handbook', critical revision and final approval of manuscript.

Competing interests: The third author [JH] is the author of 'The Little Parent Handbook.

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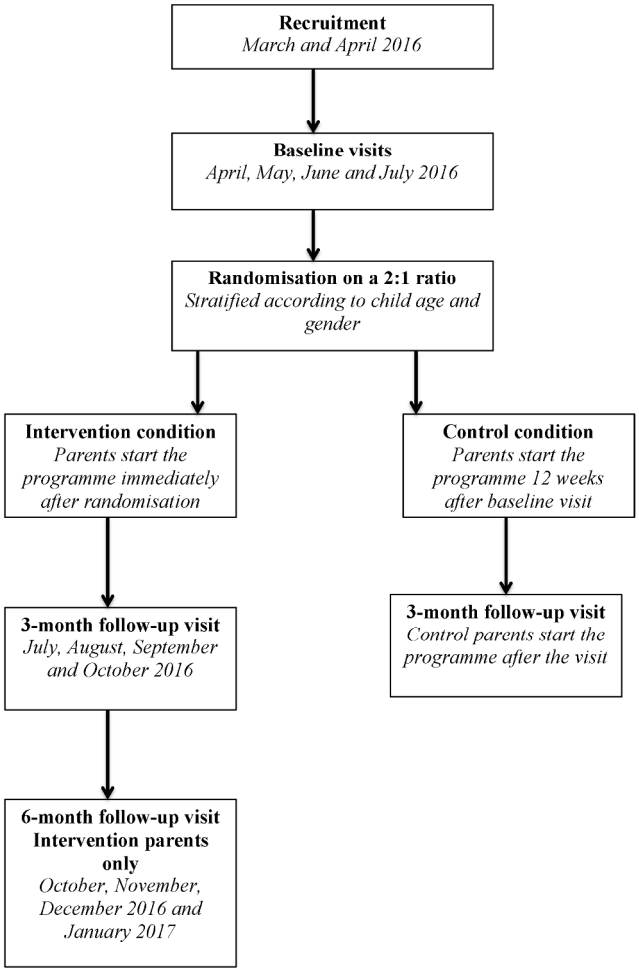
Figure legend: Participant flow chart



Participant flow chart

209x297mm (300 x 300 DPI)

COLEG GWYDDORAU IECHYD AC YMDDYGIAD
COLLEGE OF HEALTH AND BEHAVIOURAL SCIENCES

YSGOL SEICOLEG
SCHOOL OF PSYCHOLOGY

PRIFYSGOL BANGOR UNIVERSITY

Study Participant Identification Number:

PARENT CONSENT FORM

Title of the Project: Evaluation of an online parenting programme based on 'The Little Parent Handbook'

Name of Researcher: _____ Please initial box

1. I confirm that I have read the information sheet dated…….. for the above study. I have had the opportunity to consider the information provided and have had questions answered satisfactorily by the researcher. ☐
2. I understand that my participation in this research study is voluntary and that I am free to withdraw at any time without having to give an explanation, without my legal rights being affected. ☐
3. I understand that the researcher will ask me to fill out questionnaires. ☐
4. I understand that the researcher will undertake a 30-minute observation of myself interacting with my child. ☐
5. I understand that I will be asked to keep on-going weekly records about my child. ☐
6. I understand that I will need an internet connection in order to participate in this online study. ☐
7. I understand that the study will last for 10 weeks and I will have one week to complete each section of the online programme. ☐
8. I understand that all information will be kept confidential unless any matter(s) regarding child protection issues arise. ☐
9. I agree to take part in the above study. ☐

Name of participant:	Date:	Signature:
_____	_____	_____
Name of person taking consent:	Date:	Signature:
_____	_____	_____

PRIFYSGOL BANGOR
ADEILAD BRIGANTIA,
FFORDD PENRALLT,
BANGOR,GWYNEDD, LL57 2AS

FFÔN: (01248) 382211

BANGOR UNIVERSITY
BRIGANTIA BUILDING,
PENRALLT ROAD,
BANGOR, GWYNEDD, LL57 2AS

TEL:(01248) 382211
Registered charity number: 1141565

ATHRO/PROFESSOR JOHN PARKINSON BA, PhD
PENNAETH YR YSGOL/HEAD OF SCHOOL

EBOST: seicoleg@bangor.ac.uk
EMAIL: psychology@bangor.ac.uk

www.bangor.ac.uk www.bangor.ac.uk/psychology

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description
Administrative information		
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym **(page 1)**
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry **(page 3)**
	2b	All items from the World Health Organization Trial Registration Data Set **(not applicable)**
Protocol version	3	Date and version identifier **(page 1)**
Funding	4	Sources and types of financial, material, and other support **(page 1)**
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors **(page 1)**
	5b	Name and contact information for the trial sponsor **(page 1)**
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities **(page 23)**
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) **(not applicable – all work carried out by the authors)**
Introduction		
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention **(pages 3 – 7)**
	6b	Explanation for choice of comparators **(page 18-19)**
Objectives	7	Specific objectives or hypotheses **(pages 7–8)**

Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) **(page 8)**
Methods: Participants, interventions, and outcomes		
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained **(page 8)**
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) **(page 8-9)**
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered **(pages 10–15)**
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) **(no criteria for discontinuing treatment)**
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) **Not applicable**
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial **Not applicable**
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended **(pages 15-18)**
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) **(insert figure on page 20)**
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations **(page 18-19)**
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size **(pages 9-10)**
Methods: Assignment of interventions (for controlled trials)		
Allocation:		

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions **(pages 19-20)**
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned **(pages 19-20)**
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions **(pages 19-20)**
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how **(page 20)**
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial **(page 20)**
Methods: Data collection, management, and analysis		
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol **(pages 18)**
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols **(page 18)**
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol **(page 18)**
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol **(page 20)**
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses) **(page 20)**
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) **(page 20)**

Methods: Monitoring

Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed **Not applicable**
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial **Not applicable**
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct **Not applicable**
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor **(process will not be independent from Bangor University)**

Ethics and dissemination

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval **(pages 2-3)**
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators) **(authors will contact relevant parties if any changes to protocol should occur)**
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) **(pages 9-10)**
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable **Not applicable**
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial **(all data will remain confidential before, during and after the trial)**
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site **(page 23)**
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators **(only the authors will have access to the data)**

Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation **Not applicable**
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions **(pages 21-22)**
	31b	Authorship eligibility guidelines and any intended use of professional writers **Not applicable**
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code **No plans**
Appendices		
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates **Uploaded with submission**
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable **Not applicable**

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

Evaluation of the COPING Parent online universal programme: Study protocol for a pilot randomised controlled trial

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Primary Subject Heading:	Evidence based practice
Secondary Subject Heading:	Public health
Keywords:	Clinical trials < THERAPEUTICS, STATISTICS & RESEARCH METHODS, Child & adolescent psychiatry < PSYCHIATRY

Title: Evaluation of the COPING Parent online universal programme: Study protocol for a pilot randomised controlled trial

Authors: Dawn Adele Owen, Nia Griffith, Judy Hutchings

Author details:

Centre for Evidence Based Early Intervention, School of Psychology, Nantlle Building, Normal Site, Bangor University, Bangor, Gwynedd, LL57 2PZ, UK (01248 383 758).

Email: dawn.a.owen@bangor.a.uk

School of Psychology, Wheldon Building, Room 113, Bangor University, Bangor, Gwynedd, LL57 2PZ, UK.

Email: n.griffith@bangor.ac.uk

Centre for Evidence Based Early Intervention, School of Psychology, Nantlle Building, Normal Site, Bangor University, Bangor, Gwynedd, LL57 2PZ, UK.

Email: j.hutchings@bangor.ac.uk

Version 4: 24/02/2017

Keywords: child behaviour, online parenting programme, randomised controlled trial, positive parenting, and health care services

Word count: 5,033

Trial Sponsor: Bangor University, Brigantia Building, College Road, Bangor, LL57 2AS

Abstract

Introduction: The COPING parent online universal programme is a web-based parenting intervention for parents of children aged 3-8 with an interest in positive parenting. The programme focuses on strengthening parent-child relationships and encouraging positive child behaviour. This trial will evaluate whether the intervention is effective in increasing the use of positive parenting strategies outlined in the programme using parent report and blind observation measures.

Methods and analysis: This is a pilot randomised controlled trial with intervention and wait-list control conditions. The intervention is a ten-week online parenting programme to promote positive parent-child relations by teaching core social learning theory principles that encourage positive child behaviour, primarily through the use of praise and rewards. Health visitors and school nurses will circulate a recruitment poster to parents of children aged 3-8 years on their current caseloads. Recruitment posters will also be distributed via local primary schools and nurseries. Parents recruited to the trial will be randomised on a 2:1 ratio to intervention or wait-list control conditions (stratified according to child gender and age). The primary outcome measure is positive parenting as measured by a behavioural observation of parent-child interactions using the Dyadic Parent-Child Interaction Coding System. Secondary outcomes include parent report of child behaviour, and self-reported parental sense of competence, parenting behaviour and parental mental health. Data will be collected at baseline and three months later (post-intervention) for all participants and six months post-baseline for the intervention group only. ANCOVA will be the main statistical method used.

Trial registration: Current Controlled Trials ISRCTN89370147 (May 5th 2016).

Strengths and limitations

- This is a randomised controlled trial (RCT) with a wait-list control group.
- The behavioural observations will incorporate an inter-rater reliability component (20% of all observations at each time point).
- Once randomised, intervention parents start the online programme immediately thus reducing the amount of time spent waiting for the intervention.
- A limitation of this study is internet based only without any additional support and parents are required to log in each week and engage with the programme. This may result in some parents not fully engaging and the potential loss of follow-up data.
- Due to time and funding constraints, this pilot trial aims to enroll sixty parents, which is a fairly small sample size not based on a power calculation.
- Funding and time constraints do not allow for a follow-up beyond 6 months.

Background

Societal changes are presenting new challenges for parents that can impact on parent-child relations, child behaviour and parenting style. For example increased time spent playing video games impacts on child mental health and social relationships [1] and changes in marital status/family structures including divorce affect children's social and emotional competence [2] and can reduce parental competencies [3]. Dysfunctional parenting is a key factor in the subsequent development of problematic child behaviour [4].

Minor child problem behaviours can develop into significant problems unless addressed whilst children are still young [5, 6]. Conduct problems have a significant impact on children's functioning and quality of life [7] with up to 50% of children and young people with conduct disorder developing antisocial personality disorder [8, 7]. It is therefore

important to provide early universal support to all parents to help them to address the small behavioural challenges faced by parents and prevent them from progressing into longer-term ones.

Increases in the numbers of children with identified early onset of behavioural difficulties have resulted in health visitors and school nurses spending much of their time supporting families with children at significant risk of poor outcomes [9], reducing their ability to provide more general support to all families [10]. A survey of health visitors and school nurses reported that 53% of health visitors saw between 21-50, and 46% of school nurses saw between 50-99 children with emotional or behavioural problems each week [9]. These growing demands on health visitors and school nurses' time reduces their ability to support all parents at a time when parents are bringing up children in a rapidly changing world with additional challenges [1].

The positive parenting practices that support children's development are well established [11] and these include relationship building strategies through time spent in play or joint activities with children, praise and reward to encourage positive child behaviour and positive parental role modelling [12]. However, evidence-based support for parents is not universally available and changing demands on parents make it important to provide all parents with access to evidence-based information.

Technology has the potential to provide knowledge about key parenting skills, reduce pressures on services; particularly those delivered by heath visitors and school nurses, and offer flexible access [13, 14, 15]. Access to technology is now feasible for many parents due to increased availability of the internet [16]. In 2016, 89% of households in Great Britain

(23.7million) had access to the internet, an increase from 86% in 2015 [17]. The majority of parents (75%) now use social media to obtain parent-related information [18] with over eight million people visiting an online parenting information and advice website every month [19].

The accessibility and convenience of access to the web has introduced the opportunity for web-based delivery preventive behavioural interventions for health promotion [20, 21]. Accessing the internet has become easier with cheaper internet providers and the availability of devices such as mobile phones and tablets. The internet provides individuals with a useful source of advice and/or support, and offers convenient and flexible access within the home. This has the potential to reduce the burden on health care service providers [22].

Although limited in number, web-based interventions have been shown to be effective in achieving a wide range of positive outcomes to promote healthy behaviours including smoking cessation and weight-loss [23, 24, 25], suggesting that the web is an effective means of providing behaviour change advice. There is evidence demonstrating increased positive parenting following web-based interventions [26], however, high attrition rates have been reported [27], with many participants starting, but not completing programmes [13]. Universal parenting programmes in general, including web-based, have not yet been extensively researched [28]. Early indications have suggested potential benefits of web-based support [26] however more research is needed.

Rationale

The Coping (**Co**nfident **P**arent **In**ternet **G**uide) web based parenting programme, is based on the content of 'The Little Parent Handbook' [12], and provides information and activities based on core social learning theory principles associated with positive parenting practices

and good child outcomes to parents of children aged 3-8 years. The study will explore the delivery of the programme, parental satisfaction and engagement with the programme and whether it is effective in demonstrating increased use of positive parental practices in parents of children with a wide age range and varying behavioural patterns.

Aims and Objectives

The aim of this trial is to conduct a pilot randomised controlled trial on the effectiveness of an online parenting programme, for parents of children aged 3-8 years who would like to learn more about positive parenting by comparing outcomes for intervention and wait-list control conditions.

The key objectives are to establish whether the programmes successfully engages and retains parents; whether the programme produces statistically significant increases in positive parenting as observed in a parent-child observation when compared to wait-list control parents; and to determine whether the online programme produces any changes in secondary outcomes (parent-reported child behaviour, parent self-reported sense of competence, behaviour and mental health). The study hypotheses are:

i. the online parenting programme will lead to significant increases in the use of positive parenting strategies as displayed in the behavioural observation coded using Dyadic Parent-Child Interaction Coding System [29]
ii. the online programme will significantly increase positive self-reported parenting skills, parental sense of competence and parental mental health
iii. the online programme will lead to reduction in parent-reported levels of child problem behaviour as reported using the Eyberg Child Behaviour Inventory [30]

Methods/Design

Trial design

This pilot RCT will explore the effectiveness of an online parenting programme. Parents of children aged 3-8 years who would like to learn more about positive parenting will be randomly allocated to the intervention condition with immediate access to the programme or to a 3-month wait-list control condition on a 2:1 ratio. Self-report and observational data will be collected in parents' homes during home visits and parents will access the programme at home.

Eligibility criteria

To be eligible for the study parents must have a child aged between 3-8 years, be able to understand English (as the programme is only currently available in English) and be able to access the internet on a PC, laptop or tablet. The software does not yet support smartphones. Parents who are currently receiving support from services are also invited to participate (they will be asked to record which services they are receiving and the duration). Individuals will be excluded from the study if a parent does not have a child aged between 3-8 years, does not understand English and does not have access to the internet.

Recruitment

Health visitors and school nurses in Gwynedd and Anglesey (North-West Wales) will approach parents of children aged 3-8 years on their own caseloads and describe the online programme and the research trial. If parents decide that they might want to sign up for the study, they will be asked by the health visitor/school nurse to complete a note of interest form, that will be sent to the research office at Bangor University, giving consent for a member of the research team to contact the parent.

On receipt of the note of interest form, a member of the research team will contact the parent to arrange a convenient time to visit and discuss the project further. The researcher will go through the information sheet with the parent during this home visit and ensure that any questions are answered. If the parent is happy to continue, the researcher will obtain informed consent from the parent to participate in the study. Only when consent has been obtained will the researcher proceed to ask the parent to fill out the self-report measures and take part in a 30-minute behavioural observation.

In addition to health visitors and school nurses approaching parents on their caseloads, recruitment posters will be distributed in primary schools and nurseries in Gwynedd, Anglesey, Conwy and Denbighshire. An e-mail address and a contact telephone number will be provided on the recruitment poster so that interested parents can contact the research team directly. Parents will either be sent a detailed information sheet via e-mail or the researcher will discuss the study in depth over the telephone. If parents would still like to participate, arrangements will then be made for a home visit to discuss the study further. Similarly, parents who hear about the study through word of mouth can contact the research team for further information regarding the trial.

It is expected that both forms of recruitment (poster and health visitor/ school nurse) will attract parents from varying socioeconomic backgrounds who are experiencing varying levels of child problem behaviour. For the purpose of this pilot trial, baseline characteristics of all parents will be reported and compared with the population as a whole. Additionally, the percentage of parents recruited from each source will be reported and their characteristics compared in order to explore the effects of the intervention for the whole sample.

Intervention

Trials conducted by Hutchings and colleagues during the 1990s [31, 32] with parents and health visitors demonstrated positive outcomes from teaching effective behavioural strategies to parents of children with challenging behavior for both clinically referred and pre-school prevention populations. Significant overall improvements were found for intervention families on measures of child behaviour, parenting practices and maternal mental health [31, 33]. As part of these trials intervention parents were provided with help sheets that were subsequently published as 'The Little Parent Handbook' [12]. These trials were multi-component trials and so it is difficult to establish the true extent of the effectiveness of the parent help-sheets, however they contained the evidence based behavioural principles on which the interventions were based.

The LifeGuide software, developed at the University of Southampton [34], was used in the creation of the online parenting programme. The aim of LifeGuide is to continuously develop, evaluate and disseminate a set of tools that will allow researchers to flexibly create and modify online behaviour change interventions [35]. LifeGuide software allows researchers to deliver behavioural principles both through programme delivery (text message prompts etc.) and programme content (The Little Parent Handbook).

Features of the online parenting programme include automated feedback based on individual performance, online praise messages for spending time with their child, text message reminders to access the next session, and multiple-choice quizzes to test knowledge. The programme also enables the tracking of individual usage data (which can be extracted into Microsoft Excel), including the number of log in, time spent on each page and the number of chapters completed.

The programme introduces evidence-based behavioural principles that have been shown to be effective in strengthening parent-child relations and encouraging positive child behaviour [36]. A small-scale feasibility study of the online parenting programme was conducted at the end of 2015 with the aim of providing user feedback prior to conducting this pilot RCT trial. The study had no measures and participants were not randomised, instead twenty participants were asked to complete the intervention and fill out a feedback form. Overall, feedback was very positive with the majority of participants reporting that they would recommend the programme to parents of children aged 3-8 years. Minor modifications were made based on the feedback, these include text message prompting to remind parents to log-in to subsequent sessions, more video examples of positive parenting and the option to look back over previously completed chapters again. The intervention consists of ten chapters, eight content and two revision chapters. The topics are:

i. Spending special time with your child through play
ii. Encouraging good behaviour through praising
iii. Encouraging good behaviour through rewarding
iv. How to get better at giving instructions [part 1]
v. How to get better at giving instructions [part 2]
vi. Revision [a review of chapters 1-5]
vii. Ignoring problem behaviour
viii. Teaching your child new behaviours
ix. How to develop your child's language skills
x. Revision [a review of chapters 1-9]

Intervention parents will be provided with a link to the website and a username and password. Contact details of an administrator will be provided in case any parent requires technical support during the programme. Parents will be asked to log in and complete one chapter each week, each chapter will take approximately thirty minutes to complete. The software ensures that parents have completed each chapter before they can move on to the next one; they are not required to complete the chapter in one sitting. Log in details allow parents to access the programme as many times as they wish. The intervention has been programmed to take parents to the last page that they viewed on the next occasion that they log in to avoid parents having to start the programme from the beginning. In order to give parents sufficient time to practice the principles outlined in the individual chapters, the intervention has been programmed so that there will be a minimum five-day gap between each chapter. If parents log in before the five days have elapsed, they will be offered the opportunity to look back over previously completed chapters again.

The programme asks parents to practice the skills presented in the chapter with their child at home. Each chapter concludes with a suggested practice activity. Parents are also encouraged to keep paper records detailing their activities. Parents can also record online each week how many times they have played with their child by selecting the amount of times from a drop-down menu. The programme encourages parents to spend more time playing with their child in order to strengthen their relationship, and they are continuously reminded to engage in this activity throughout the programme both by praise messages and by being prompted to record the amount of time spent playing. A praise message congratulates the parent for spending time with their child if they report spending time with their child during the past week, or since the last time they logged in. If parents do not report having spent time with their child

during the past week, a prompt message appears reminding them of the importance of this activity.

Each chapter covers an individual behavioural principle that aims to strengthen the parent-child relationship. Parents read through information (or listen via an audio button if they prefer) and watch video examples of positive parenting. The video clips are short in length (all are less than one minute long) allowing the opportunity for multiple viewing. At the end of each chapter there is a longer video and parents are asked to answer three questions based on the video clip (by selecting yes or no) in order to develop their observational skills and to encourage them to identify positive child behaviours. For example, at the end of chapter two (praising positive behaviour) parents are prompted to watch a video of a parent giving her child a specific labelled praise, and then answering three questions based on the video; (1) did the parent praise the child immediately? (2) Was the parent close to the child when praising? (3) Did the parent share positive feelings when praising? A score out of three and the correct answers are provided for the responses to the videos. Each chapter ends with a multiple-choice quiz to test parents' knowledge and understanding of key principles. Parents will be given online automated feedback based on their quiz scores in addition to the correct answers. Parents also have an option to download and print a summary sheet for each chapter.

Parents will be given an opportunity to receive text message prompts to help keep them on track. If they would like to receive text messages, they will be asked at the beginning of the programme to enter their mobile phone number. The programme is fully automated, and the research team will have no contact with parents during the intervention. The centre administrator can be contacted if parents require any technical assistance during the study. A

text message will be sent five days after the completion of a chapter informing the parent that the next chapter is now available. If the parent has not logged into the programme to complete the next chapter three days after it becomes available, a reminder text will be sent prompting them to log in and complete the next chapter. If a parent still has not logged in, weekly reminders will be sent. LifeGuide does not allow researchers to track how many messages parents have received, however, researchers will calculate the number of text messages each participant has received depending on the programme schedule, e.g. if a parent has not logged on after three days of the chapter becoming available they will have received one text message, etc. Therefore it will be possible to monitor the level of prompting each participant receives.

Baseline data will be collected prior to randomisation and, once completed, intervention parents will receive a notification of their status and their log in details, whilst parents in the wait-list control group will be informed that they will have access to the programme after three months. Follow up data will be collected after three moths regardless of whether intervention parents have completed the programme. Once post-intervention data has been collected, control parents will receive their log in details for the programme. On completion of both baseline and follow-up visits, families will receive a children's book as a thank you for their time. On completion of all measures, parents will receive a copy of 'The Little Parent Handbook'. Data collection will begin in April 2016 and end in February 2017.

Primary measure

The primary outcome is to establish whether the online parenting programme produces significant changes in positive parenting practices from baseline to follow-up as recorded using the DPICS. The researcher will observe the parent and child engaging in child-led play

for thirty minutes. This coding system was specifically designed to assess the quality of parent-child social interaction [37]. The DPICS has demonstrated high inter-rater reliability for parent and child behaviours, $r = 0.67$ to 1.0 and $r = 0.76$ to 1.0 respectively [37]. Direct observation was selected as the primary outcome as direct observational methods provide a more precise account of behaviour defined by the researcher and not the parent [38]. Additionally, this observational measure has been used in a number of previous studies at the centre [39, 32, 40].

There are eight DPICS parent categories summarised in terms of positive and negative parenting. Positive parenting categories comprise of direct command, labelled praise, unlabelled praise and descriptive commenting/verbal labelling. Negative parenting categories comprise of indirect command, questions, critical statement and negative command. No child categories will be recorded; child behaviour will be measured using the parent report ECBI only, as the main purpose of this study is to see whether the intervention has an affect on parental behaviour. Observational coding is continuous and records the total frequency of each category of parent behaviour for a total of thirty minutes. Inter-rater levels of reliability will be assessed for 20% of all observations at all three-time points.

Secondary measures

The following secondary outcomes will be collected at three time points by the research team for the intervention group and at two time points for the wait-list control group.

- Child behaviour as measured by the Eyberg Child Behaviour Inventory [30]. This measure is a 36-item inventory completed by the parent to assess the frequency and intensity of child behavioural problems for children aged 2-16 years, and has been used in many previous trials including several that have been conducted at the centre

[39, 31]. Factor analyses of the ECBI for both children and adolescents indicate that it is a uni-dimensional measure of conduct problem behaviours [30].

- Parenting practices as measured by the Arnold O'Leary Parenting Scale [41]. This is a 30-item inventory with three subscales measuring parental behaviour: laxness, over-reactivity and verbosity. Responses are recorded on a seven-point scale with two alternative responses to a particular parental situation. The parenting scale has been shown to exhibit adequate internal validity and test-retest reliability [41] in addition to demonstrating significant correlations with observational measures of child problem behaviour [41].
- Parental confidence as measured by the Parental Sense of Competence questionnaire [42]. This 17-item likert–scale questionnaire measures competence on two separate dimensions: satisfaction and efficacy. The satisfaction questions measure parental anxiety, motivation and frustration (for example, 'sometimes I feel like I'm not getting anything done') and the efficacy question examine competence, capability levels and problem-solving skills (for example, 'I meet my own personal expectations for expertise in caring for my child') in relation to parenting [42]. Ohan, Leung and Johnston [43] replicated the factor structure of the Parenting Sense of Competence Scale produced by Johnston and Mash [42], and provided evidence that the satisfaction and efficacy scales from this measure assess distinct aspects of parenting self-esteem.
- Parental mental health as measured by the General Health Questionnaire [44]. This is a 30-item questionnaire and each item invites one of four responses in order to assess psychiatric symptoms including social dysfunction, sleeping patterns and depression [45]. The responses include 'better than usual', 'same as usual', 'less than usual' and 'much less than usual' to questions such as 'have you found everything getting on top

of you?' and 'have you been getting edgy and bad tempered?' This measure was used as research has demonstrated the association between maternal mental health and child conduct problems [46]. Reliability coefficients of the questionnaire have ranged from 0.78 to 0.95 in various studies [47]. There have been several factor analyses of the GHQ-30 in relatively large community samples [46].

Demographic information

Demographic information will be collected from all participants at baseline prior to randomisation. The demographic questionnaire is based on the 'Personal Development and Health Questionnaire' [48] and will include data on socioeconomic status, including poverty, parental educational level and single-parent status. The questionnaire will cover the following information:

Age of parent and child, gender of parent and child, child diagnosis, parent's relationship to the child (biological or non-biological parent), parent's age at birth of first child, how many children the parent has, ages of all children, parent's current relationship status, partner's relationship to the child, housing situation, employment status, income, parent's level of education and whether they have previously attended a parenting course. An additional question regarding their internet usage is also included.

Data Collection

Members of the research team will collect parental self-report measures and observational data on parent-child interaction using the DPICS behaviour coding system, during home visits at baseline and follow-up. There is a possibility that parents will drop out of the programme before the end; nonetheless all efforts will be made by researchers to collect

follow-up data in the form of telephone contact and appointment letters. Parents will also be asked to complete a short feedback/satisfaction questionnaire at the end of the study to share their views of the programme.

The DPICS has been used in a number of studies evaluating parenting programmes [39, 41, 47]. Research team members are already trained in DPICS coding and have reached 80% inter-rater reliability across all categories. At least two coders, to establish inter-rater reliability, will code 20% of observations at each time-point simultaneously (baseline and follow-up). Frequent practice sessions and meetings will be held to discuss any matters arising and to ensure maintenance of a minimum level of 80% reliability.

Sample Size

The intention is to enroll 60 parents of children aged 3-8 years (40 to intervention and 20 to wait-list control, randomised on a 2:1 ratio). Due to limited funds and time restrictions associated with recruitment and data collection, a larger sample size would be difficult to recruit within the time frame. Additionally, this is a pilot RCT with the aim of exploring initial outcomes (in terms of measures, delivery and acceptance of the programme) with a view to conducting a larger scale trial in the future. Results from this pilot trial will give researchers initial information regarding acceptability and delivery of the programme with parents of children aged 3-8 years and should be sufficient to explore initial outcomes in terms of encouragement in the use of positive parental strategies that would inform a power calculation for a larger definitive study.

Randomisation

Once all of the data for individual parents have been collected at baseline, parents will be randomised to either the intervention or a wait-list control condition on a 2:1 ratio. This allows for the evaluation of a larger intervention sample whilst also reducing the number of parents waiting for the intervention. This design is favoured for research in this field [39]. A control condition was favoured over an alternative treatment condition as the researchers wanted to ensure that all participants received access to the intervention. The randomisation will be stratified according to child age (3-5 and 6-8 years old) and gender (male and female) using the online software 'sealed envelope'. The centre administrative assistant will undertake the randomisation process, which will require entering the participant identification number, child age and child gender. The software will then generate the decision on whether the participant has been allocated to the intervention (group 1) or control (group 2) condition. Parents will receive a letter from the administrator informing them of their group allocation and intervention parents will receive the link to the website and their log in details with this letter. Control parents will be informed that they will receive their log in details upon completion of the second home visit (post-intervention data).

(Insert Figure 1 here)

Blinding

Baseline measures will be completed prior to randomisation and parents will be asked (during home visits) not to reveal their group allocation to researchers in order, as far as possible, to keep the researchers blind to parent group allocation. However, some parents may reveal their allocation during the first follow-up home visit. In this instance, researchers will make a record of this. Due to the design of the study, it will not be possible to keep the researchers blind to group allocation at the six-month follow-up stage as they will only involve

intervention parents. However the key measures are parent report questionnaires and the frequency based behavioural observation that incorporates inter-rater reliability. If high levels of unmasking occur, a variable will be added to the analysis to control for this.

Statistical Analysis

Baseline characteristics for all parents and children will be analysed and checked for differences (if any) between the intervention and wait-list control conditions. Any differences will be recorded and accounted for the in the analysis. ANCOVA will be the main analysis method used to compare the intervention and wait-list control conditions. Any missing data will be treated using multiple imputation, a relatively flexible, general-purpose approach to dealing with missing data [49].

Discussion

This trial will provide information on the effectiveness of an online parenting programme, an intervention designed to increase positive parenting for parents of children aged 3-8 years. The effects of the intervention on child behaviour, parenting behaviour, parental mental health and parental sense of competence will also be assessed. It is hypothesised that the online programme will encourage parents to use positive parenting strategies, including spending more time with their child and praising and rewarding positive child behaviour. Additionally, it is hypothesised that the online programme will improve a range of outcomes including self-reported parenting practices, parental mental health, parental confidence and child behaviour.

This project is timely when considering the current situation with regards to rising numbers of children displaying behaviour problems [7], challenges faced by all parents and the known impact of parenting style on the establishment and maintenance child behaviour problems [47, 50, 12]. This programme could potentially be useful to parents who would like to receive additional support, but who are not living in targeted areas (such as Flying Start areas in Wales) where higher levels of parenting support are provided. A preventative universal programme available to all parents could potentially allow health care professionals more time and resources to target clinical (or at-risk) populations and also encourage parents to use well established positive parenting strategies to prevent child behaviour problems from forming. A universal preventative programme such as this could be useful in encouraging positive parenting practices for all parents and reduce the number of families seeking advice for whom no service currently exists [51].

Ethics and dissemination

The trial has received ethical approval from the NHS Betsi Cadwaladr University Health Board Ethics Committee (REC) and the School of Psychology, Bangor University REC (15/WA/0463). Publication of all outcomes will be in peer-reviewed journals and conference presentations.

Parents recruited to the trial will be notified of the results by means of a letter, and researchers will verbally present the findings to healthcare professionals who helped with recruitment. If the trial suggests that there are significant benefits, this would inform a bid for funding for a larger definitive RCT with the goal that the intervention could subsequently be made available to parents in general as a preventative programme.

Trial status

The trial is currently on going. Baseline and 3-month follow-up measures for all parents were completed in October 2016. Data is currently being collected for the 6-month follow-up of intervention parents.

Abbreviations

NICE: The National Institute for Health and Care Excellence; ONS: Office for National Statistics, ANCOVA; Analysis of Covariance; REC: Research Ethics Committee

Author's contributions

DAO: designing of the online programme, manuscript writing, gaining ethical approval, data collection, data analysis, critical revision and final approval of manuscript. NG: critical revision and final approval of manuscript. JH: author of 'The Little Parent Handbook', critical revision and final approval of manuscript.

Competing interests: The third author [JH] is the author of 'The Little Parent Handbook.

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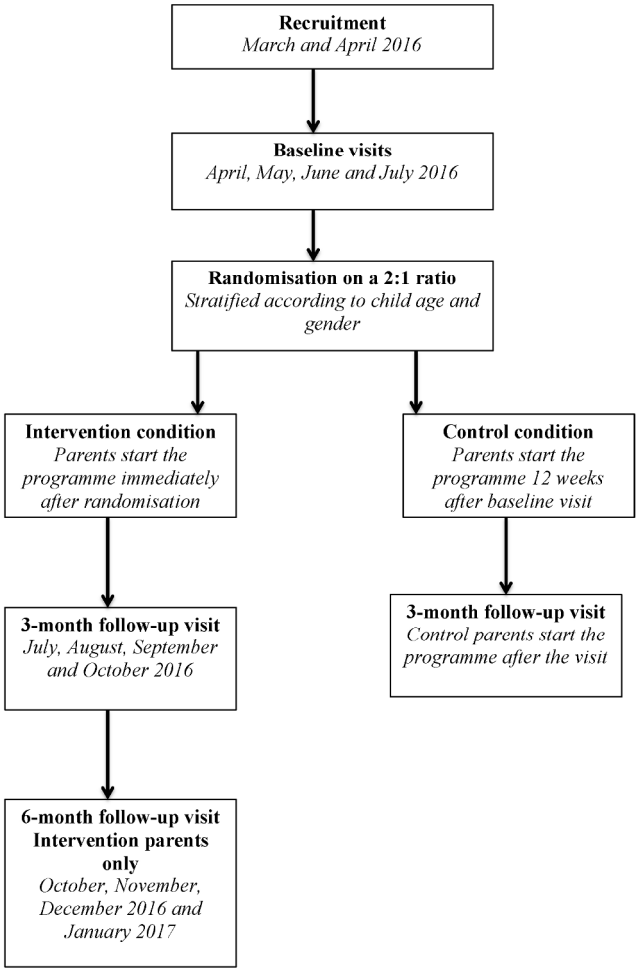
Figure legend: Participant flow chart



Participant flow chart

209x297mm (300 x 300 DPI)

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description
Administrative information		
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym **(page 1)**
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry **(page 2)**
	2b	All items from the World Health Organization Trial Registration Data Set **(not applicable)**
Protocol version	3	Date and version identifier **(page 1)**
Funding	4	Sources and types of financial, material, and other support **(page 1)**
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors **(page 1)**
	5b	Name and contact information for the trial sponsor **(page 1)**
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities **(page 21)**
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) **(not applicable – all work carried out by the authors)**
Introduction		
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention **(pages 3 – 6)**
	6b	Explanation for choice of comparators **(page 17-19)**
Objectives	7	Specific objectives or hypotheses **(page 6)**

Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) **(page 7)**
Methods: Participants, interventions, and outcomes		
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained **(page 7)**
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) **(page 7)**
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered **(pages 9–13)**
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) **(no criteria for discontinuing treatment)**
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) **Not applicable**
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial **Not applicable**
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended **(pages 13-16)**
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) **(insert figure on page 18)**
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations **(page 17)**
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size **(pages 7-8)**
Methods: Assignment of interventions (for controlled trials)		
Allocation:		

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions **(pages 17-18)**
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned **(pages 17-18)**
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions **(pages 17-18)**
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how **(pages 18-19)**
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial **(pages 18-19)**
Methods: Data collection, management, and analysis		
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol **(pages 16-17)**
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols **(pages 16-17)**
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol **(pages 16-17)**
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol **(page 19)**
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses) **(page 19)**
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) **(page 19)**

Methods: Monitoring

Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed **Not applicable**
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial **Not applicable**
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct **Not applicable**
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor **(process will not be independent from Bangor University)**

Ethics and dissemination

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval **(page 20)**
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators) **(authors will contact relevant parties if any changes to protocol should occur)**
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) **(page 8)**
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable **Not applicable**
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial **(all data will remain confidential before, during and after the trial)**
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site **(page 21)**
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators **(only the authors will have access to the data)**

Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation **Not applicable**
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions **(page 20)**
	31b	Authorship eligibility guidelines and any intended use of professional writers **Not applicable**
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code **No plans**
Appendices		
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates **Uploaded with submission**
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable **Not applicable**

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

COLEG GWYDDORAU IECHYD AC YMDDYGIAD
COLLEGE OF HEALTH AND BEHAVIOURAL SCIENCES

YSGOL SEICOLEG
SCHOOL OF PSYCHOLOGY

PRIFYSGOL BANGOR UNIVERSITY

Study Participant Identification Number:

PARENT CONSENT FORM

Title of the Project: Evaluation of an online parenting programme based on 'The Little Parent Handbook'

Name of Researcher: _____ Please initial box

1. I confirm that I have read the information sheet dated…….. for the above study. I have had the opportunity to consider the information provided and have had questions answered satisfactorily by the researcher. ☐
2. I understand that my participation in this research study is voluntary and that I am free to withdraw at any time without having to give an explanation, without my legal rights being affected. ☐
3. I understand that the researcher will ask me to fill out questionnaires. ☐
4. I understand that the researcher will undertake a 30-minute observation of myself interacting with my child. ☐
5. I understand that I will be asked to keep on-going weekly records about my child. ☐
6. I understand that I will need an internet connection in order to participate in this online study. ☐
7. I understand that the study will last for 10 weeks and I will have one week to complete each section of the online programme. ☐
8. I understand that all information will be kept confidential unless any matter(s) regarding child protection issues arise. ☐
9. I agree to take part in the above study. ☐

Name of participant:	Date:	Signature:
_____	_____	_____
Name of person taking consent:	Date:	Signature:
_____	_____	_____

PRIFYSGOL BANGOR
ADEILAD BRIGANTIA,
FFORDD PENRALLT,
BANGOR,GWYNEDD, LL57 2AS

FFÔN: (01248) 382211

BANGOR UNIVERSITY
BRIGANTIA BUILDING,
PENRALLT ROAD,
BANGOR, GWYNEDD, LL57 2AS

TEL:(01248) 382211
Registered charity number: 1141565

ATHRO/PROFESSOR JOHN PARKINSON BA, PhD
PENNAETH YR YSGOL/HEAD OF SCHOOL

EBOST: seicoleg@bangor.ac.uk
EMAIL: psychology@bangor.ac.uk

www.bangor.ac.uk www.bangor.ac.uk/psychology