Cover Page

The Nurtured Heart Parenting Intervention for Children's Behavioural Problems: A Single Case Design

Protocol Version 1.2

Date: 08.02.2022

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UNIVERSITY OF LINCOLN

PROTOCOL

The Nurtured Heart Parenting Intervention for Children's Behavioural Problems: A Single Case Design

Nurtured Heart parenting intervention for child behavioural problems

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Date: 08.02.2022

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SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement(s).

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

Chief Investigator:

Signature: ..... Date: ..31..../..01.../..2022...

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FUNDER DETAILS

FUNDER(S)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**
Higher Education England	Student research – no specific project funding. This research project is being completed in partial fulfilment of the Doctorate in Clinical Psychology programme, funded by Health Education England

STUDY SUMMARY

Study Title	The Nurtured Heart Parenting Intervention for Children's Behavioural Problems: A Single Case Design
Study Design	The study will use a non-concurrent across-participant multiple baseline A-B single case design.
Study Participants	Participants will be parents/carers of children who have been referred to National Health Service (NHS) specialist children's services. Participants will be recruited from the waiting lists of children's services at two NHS trusts in the East Midlands.
Eligibility Criteria	Inclusion criteria: the parent/carer identifies their child's behaviour as problematic; the child's behavioural problems are one of the primary presenting problems; and the referred child is aged between three and eleven years old. Exclusion criteria: the child has a diagnosis of developmental delay or learning disability; the family is receiving active multi-agency involvement; and the participant is unable to read/speak English fluently.
Planned Sample Size	The planned number of participants is six.
Study Duration	The duration of the intervention for participants is 13 weeks: 3 weeks baseline data collection, 6 weeks intervention, post-intervention follow-up 4 weeks after intervention completion. Total participant duration from first contact with participants will be approximately 16 weeks. The total expected duration of the study is 13 months. Planned start date: February 2022 (dependant on approval by ethics committee). The research will be submitted in the form of a thesis in partial fulfilment of the requirements for the Trent Doctorate in Clinical Psychology. Planned submission date: February 2023.
Objectives	The primary research question is: When delivered in a guided self-help format, is the NHA effective in reducing parent-reported children's behavioural problems? The secondary research questions are: 1. When delivered in a guided self-help format, is the NHA effective in: a. reducing negative parenting practices? b. increasing parental reflective functioning? 2. To what extent is the NHA a feasible and acceptable intervention for parents of children with behavioural problems when delivered in a guided self-help format?
Outcome Measures	Measures: Brief Problem Monitor (BPM; Achenbach et al., 2011), Psychological Outcomes Profiles (PSYCHLOPS; Ashworth et al., 2009), Multidimensional Assessment of Parenting Scale (MAPS; Parent & Forehand, 2017); Parental

	Reflective Functioning Questionnaire (PRFQ; Luyten et al., 2017), Warwick-Edinburgh Mental Well-Being Scale (WEMWBS; Tennant et al., 2007) A semi-structured change interview (based on Rodgers and Elliott (2015) will be completed with participants 4 weeks post-intervention.
Data Analysis	Visual analysis and calculations of reliable and clinically significant change will be used to analyse the quantitative data. Framework analysis as outlined by Gale et al. (2013) will be used to analyse the change interviews.

KEY WORDS

Nurtured Heart Approach; parenting; child behavioural problems; single case design.

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LIST OF ABBREVIATIONS

AE	Adverse Event
CAMHS	Child and Adolescent Mental Health Service
CF	Consent Form
CI	Chief Investigator
CRF	Case Report Form
DClinPsy	Doctorate of Clinical Psychology
EudraCT	European Clinical Trials Database
GCP	Good Clinical Practice
GP	General Practitioner
HCPC	Health and Care Professions Council
HRA	Health Research Authority
ICF	Informed Consent Form
IRAS	Integrated Research Application System
ISF	Investigator Site File (This forms part of the TMF)
ISRCTN	International Standard Randomised Controlled Trials Number
LIH	Lincoln Institute for Health
NHA	Nurtured Heart Approach
NHS	National Health Service
NHS R&D	National Health Service Research & Development
NICE	National Institute for Health and Care Excellence
PI	Principal Investigator
PIS	Participant Information Sheet
PRF	Parental Reflective Functioning
RCT	Randomised Control Trial
REC	Research Ethics Committee
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
SUCAP	Service User and Carer Advisory Panel
TMF	Trial Master File
UoL	University of Lincoln

STUDY MANAGEMENT

ROLE OF STUDY SPONSOR AND FUNDER

The sponsor of the study is the University of Lincoln.

The Chief Investigator has overall responsibility for the study and shall oversee all study management.

STUDY BACKGROUND and RATIONALE

Behavioural problems are common in childhood; estimates suggest that between 5% and 14% of children exhibit behavioural difficulties (Green et al., 2005; Merikangas et al., 2009). In the UK, 30% of general practitioner (GP) child consultations and the majority of referrals to children's mental health services are for behavioural problems (National Institute for Health and Care Excellence (NICE), 2017). It is clear, therefore, the scale of the problem is significant.

The term "behavioural problems" is widely used but its precise meaning is often not clear. However, defining what is meant by behavioural problems is difficult for several reasons. Problematic behaviour is age and context dependent; tantrums are developmentally appropriate at the age of two but not past the age of four (Gardner & Shaw, 2008). There is also a subjective judgement as to what behaviour presents a problem, and for whom.

Achenbach (1966) identified two broad dimensions of behaviour in children: externalising and internalising behaviours. Externalising behaviours are generally defined as aggression, cruelty and rule-breaking behaviours (Achenbach, 1978; Achenbach & Edelbrock, 1979; Frick et al., 1993). Unlike internalising behaviours such as anxiety, which are most problematic for the child themselves, externalising behaviours mainly present problems for others (Carr, 2016). The focus of this study will be on externalising behaviour in childhood.

Behavioural problems in childhood have numerous negative correlates in adolescence and adulthood. Children demonstrating higher levels of externalising behaviour have increased risks of poor school attendance, poor educational attainment, anxiety and mood disorders, substance misuse, unemployment, and criminal offending (Colman et al., 2009; Kratzer & Hodgins, 1997). Consequently, childhood behavioural problems have a pervasive impact on both individual and societal levels.

Development of the problem

The aetiology of childhood behavioural problems is complex due to the bidirectional relationship between a child and their environment, incorporating genetic, family and socioeconomic factors (Jaffee & Price, 2007; NICE, 2017). The role of parenting has been the focus of much research. Critical, punitive and inconsistent parenting has been grouped together into a parenting dimension labelled negative parenting practices (Parent & Forehand, 2017). These negative parenting practices consistently predict increased externalising behaviour in children (Gryczkowski et al., 2010; Reitz et al., 2006; Scaramella et al., 2008).

Patterson's (1982) coercion theory proposed a mechanism through which parents' behaviour contributes to the development and maintenance of behavioural problems. Reinforcement, a central component of coercion theory, is any consequence that increases the likelihood of a behaviour occurring again; positive reinforcement is the introduction of a rewarding stimulus while negative reinforcement is the removal of an aversive stimulus (Ramnero & Törneke, 2011).

Coercion theory states a parent initially positively reinforces a child's undesirable behaviours by rewarding these with attention, in the absence of desirable behaviours receiving attention. The child's continued aversive behaviour is then negatively reinforced by eventual withdrawal of the parent (for example, due to frustration). Over time, parent and child develop mutually reinforcing patterns of increasingly aversive behaviour (Eddy et al., 2001; Smith et al., 2014).

Recently, however, research has also identified parents' ability to understand their own mental states, and that of their children, as fundamental to parenting behaviour (Camoirano, 2017). Parental reflective functioning (PRF) is a relatively new construct that captures parents' mentalising ability specifically in relation to their children (Luyten et al., 2017).

Research into the relationship between PRF and children's behaviour is in its infancy. However, there is already evidence to suggest that lower levels of parental reflective functioning are correlated with: more negative parenting practices (Riva Crugnola et al., 2018); increased aggression in infancy (Smaling et al., 2017); increased externalising behaviours in childhood (Ensink et al., 2016); and poorer emotional regulation skills (Nijssens et al., 2020).

Moreover, because all behaviour is perceived subjectively, the way a parent makes sense of their child's behaviour becomes important. Staines et al. (2019) found that following a parenting programme which increased PRF, adoptive parents attributed children's problematic behaviour less to behavioural problems and more to emotional and peer-related difficulties. When considering childhood behavioural problems, a parent's perception of their child's behaviour consequently appears to be an important factor.

Interventions

Parenting interventions are a NICE recommended and well-evidenced approach for reducing childhood behavioural problems for children aged three to eleven years old (NICE, 2017). Parent training programmes differ in their focus, with the majority placing emphasis on behavioural and psychoeducational strategies that aim to reduce ineffectual and detrimental parenting practices (Tully & Hunt, 2016).

Suchman et al. (2006), however, emphasised the importance of including relational aspects in parent training programmes. Improving parents' behaviour management skills without also developing emotional and relational skills limits the potential impact of parenting interventions (Suchman et al., 2004). Emotionally attuned parenting is fundamental to children's wellbeing and where this is lacking, children tend to have significantly poorer outcomes (Carr, 2016), including exhibiting externalising behaviours. Consequently, interventions are increasingly targeting emotional and relational aspects of parenting (Camoirano, 2017).

The Nurtured Heart Approach (NHA; Glasser & Easley, 2016) is a parenting training programme that targets parents of children with behavioural problems. It is widely used in the USA and increasingly in the UK, currently in National Health Service (NHS) children's mental health services in Lincolnshire. The NHA can be delivered as a one to one, group, or self-help intervention (Glasser, 2016), and is a short-term intervention usually delivered in four to six sessions.

The NHA incorporates three stands (Glasser & Easley, 2016): refusing to energize negativity; energising success; and implementing limits and consequences. Glasser and Easley (2016) do not provide any theoretical grounding or empirical evidence, but state the NHA was developed based on clinical experience. Although not explicitly acknowledged, however, the NHA clearly draws on several psychological theories. The three stands are based upon well-established and well-evidenced behavioural principles, consistent with coercion theory (Hektner et al., 2013).

The NHA also targets parents' insight and understanding of their child (Glasser & Easley, 2016). Emphasis is placed the child's perspective and strengths through illustrative examples and practice tasks. Parents are also required to reflect on their own mental states, learning to "self-reset" when experiencing heightened emotion (Glasser, 2016, p. 39). In this way, the NHA is introducing and reinforcing parents' ability to understand their own and their child's mental states, as captured by the construct of parental reflective functioning.

Despite the increasing use in clinical practice, the NHA currently has an extremely limited evidence base. The only published research study found that the NHA reduced negative parenting practices, as well as increasing parents' perception of their children's strengths (Brennan et al., 2016). However, the study used a quasi-experimental design which Brennan et al. (2016) acknowledged was a fundamental weakness which prevented firm conclusions being drawn.

Nuño et al. (2019) proposed a randomised control trial (RCT) protocol for assessing the effectiveness of the NHA but to date no RCT nor any other experimental design has been used to research the NHA. Moreover, while Hektner et al. (2013) and Kausik and Hussain (2020) have proposed conceptual frameworks, neither study hypothesised mechanisms of change. Consequently, there is a clear need for further research into the NHA.

A meta-analysis exploring the impact of self-directed parenting interventions compared to therapist led parenting interventions for child externalising behaviour found both approaches to be effective in reducing children's behavioural problems with no significant difference between modes of delivery (Tarver et al., 2014). In the context of public services requiring the most cost effective service delivery due to financial constraints (Robertson et al., 2017), self-help interventions can offer a valuable alternative to more resource intensive modes of delivery. Therefore, the focus of this research will be on the self-help delivery of the NHA.

Greater understanding of the effectiveness and mechanisms of the NHA delivered in a self-help format will add to the evidence base around parenting interventions for externalising behavioural problems in children. In turn, this can allow current services to make informed about the most appropriate interventions which is particularly important given the NHA is currently being used in NHS services.

STUDY OBJECTIVES AND PURPOSE

PURPOSE AND PRIMARY OBJECTIVES

The purpose of the study is to increase the evidence base for the NHA parent training programme.

The primary objective of this study is to explore the effectiveness of the Nurtured Heart Approach parent training programme when delivered in a guided self-help format. Therefore, the primary research question is:

When delivered in a guided self-help format, is the NHA effective in reducing parent-reported children's behavioural problems?

SECONDARY OBJECTIVE(S)

The secondary research questions are:

1. When delivered in a guided self-help format, is the NHA effective in:
    a. reducing negative parenting practices?
    b. increasing parental reflective functioning?
2. To what extent is the NHA a feasible and acceptable intervention for parents of children with behavioural problems when delivered in a guided self-help format?

OUTCOME MEASURES/ENDPOINTS

PRIMARY OUTCOME MEASURE/ENDPOINT

The primary outcome measure is parent-reported child behavioural problems and will be measured at baseline, throughout the intervention and post-intervention four weeks after the intervention has been concluded.

Primary outcome measure

The Brief Problem Monitor (BPM), a short version of the Child Behaviour Checklist (CBCL; Achenbach & Rescorla, 2001), will be used to measure parent-reported child behavioural problems. While both versions have been used extensively in research, the 113 item CBCL is too long to repeat regularly. The BPM is more suitable than the alternative Strengths and Difficulties Questionnaire (SDQ; Goodman, 1997) because of the difference in factor structures; the externalising scale of the BPM is more consistently supported in factor analyses than the five-factor structure of the SDQ which has externalising behaviour represented across three different subscales (McCrory & Layte, 2012).

SECONDARY ENDPOINTS/OUTCOMES

The secondary measures include a parenting practice measure, parental reflective functioning measure, a general wellbeing measure and an ideographic measure to capture parents' perception of the problems and assess any change. A change interview will also be completed with participants.

Parenting practice measure

The Multidimensional Assessment of Parenting Scale (MAPS) uses a two-factor structure that assesses positive (e.g. nurturing, attuned) and negative (e.g. hostile, punitive, critical) parenting practices (Parent & Forehand, 2017). The MAPS takes approximately ten minutes to complete every session, which is a time burden for participants. There are very few alternatives, however, that are shorter and retain adequate psychometric properties. Relying on a self-report measure without observations of parenting is a limitation, although there is evidence to suggest that self-report measures of parenting do correlate with independent observations (Hawes & Dadds, 2006). An observational element is not included because this would impact the feasibility of the study in the given timescale, particularly in the context of the global pandemic. The MAPS will be shortened for repeated measurement purposes. This will be done by taking the top 3 items from the MAPS positive scale and the top 3 from the negative and using that as a proxy process measure. What constitutes 'top' can be established by either face-validity, relative factor loadings of each item derived from the original scale development, or a combination of both.

Parental reflective functioning measure

The Parental Reflective Functioning Questionnaire (PRFQ) will be used to assess parental reflective functioning. The PRFQ has not been validated by developers for parents of children aged six to eleven (Luyten et al., 2017). However, there is preliminary evidence that the measure is valid in children up to the age of ten (Pazzagli et al., 2018). Consequently, the PRFQ will be used for participants of this study as, despite the limited validation in age range of the PRFQ, it is the only measure in existence that captures parental reflectivity.

Ideographic measure

An ideographic measure is included to capture parents' perception of the problems and assess any change. The Psychological Outcomes Profiles (PSYCHLOPS; Ashworth et al., 2009) items will be generated with each participant at the beginning of the baseline phase. The PSYCHLOPS is more proportionate than the Personal Questionnaire (Elliott et al., 2016) as it focuses on two problem areas rather than ten; this will reduce the time burden on participants during the generation of items and completion of the measure.

General wellbeing measure

Understanding general wellbeing is important as it is likely to impact parenting behaviour. The Short Warwick-Edinburgh Mental Well-Being Scale (SWEMWBS; Tennant et al., 2007) will be used instead of the General Health Questionnaire (GHQ-12; McCabe et al., 1996) because the GHQ-12 primarily screens for psychopathology whereas the SWEMWBS also captures positive aspects of wellbeing.

Change interview

One month post intervention the participants will also be asked to take part in a semi-structured change interview (Rodgers & Elliott, 2015). The purpose of the interview is to capture parents' views of any changes resulting from their participation in the NHA intervention. The addition of this qualitative data will allow for a more comprehensive evaluation of the intervention.

STUDY DESIGN

The study proposes using a non-concurrent across-participant multiple baseline A-B single case design. The baseline period (A) precedes the intervention period (B), where the NHA is delivered in a guided self-help format over six weeks. Data will be collected using psychometric measures and post-intervention data

collection will also include a qualitative semi-structured change interview. Full details are given below in "Study Procedure".

DATA ANALYSIS

Visual analysis is the suggested method of analysing single case design data (Barlow et al., 2009) and consequently will be used to analyse the data resulting from this research. The data will be visually represented on graphs and examined for trends in the data indicating if and when change has occurred across the process measures for the three variables of interest. The data will also be analysed to establish if any changes are reliable and clinically significant. Assessment of reliable change identifies if change is genuine or resulting from measurement error; this will be calculated using the Reliable Change Index (Jacobson & Truax, 1991). If changes prove reliable, they will be analysed for clinical significance (Jacobson & Truax, 1991). The change interviews will be transcribed verbatim by the doctoral student and analysed using framework analysis as outlined by Gale et al. (2013). NVivo will be used to conduct the framework analysis.

Data analysis will be completed by the doctoral student with support from the research supervisors (CI and collaborator). No interim analysis are planned.

STUDY SETTING

The study will be run across two mental health trusts in the East Midlands. The specialist children's services (Child and Adolescent Mental Health Service; CAMHS) within [redacted NHS Trust] will be the primary study site. The CAMHS service consists of four locality teams across the county, all of which work together to form one service. The population being recruited from will be parents/carers of children on the waiting lists for these services. Recruitment will be supported by staff within these services who are aware of the research project and its aims.

The secondary study site will be CAMHS services within [redacted NHS Trust]. Recruitment will only occur in the secondary study site if it has not been possible to recruit sufficient participants from the primary study site. Again, recruitment will be focused on parents/carers of children on the waiting lists for CAMHS services and will be supported by clinical psychologists within CAMHS who are aware of the research project and its aims.

Across both sites the referred children of participants will remain on the waiting list, with an allocated lead professional, for the duration of the intervention. Consequently, the services will retain clinical responsibility throughout the intervention. When potential participants are identified by staff from the services, in the first instance the allocated lead professional will establish if parents/carers consent to being contacted for research purposes. If consenting to the contact, the doctoral student will then contact potential participants – see Study Procedure below for full details. Staff from the service will have no further role in the research study. However, notes from the intervention sessions will be uploaded to the record of the referred child for each service meaning staff can access session notes if they have a legitimate reason to do so. This will be made clear to participants at the outset of the study.

SELECTION OF PARTICIPANTS

ELIGIBILITY CRITERIA

Participants will be parents/carers of children who have been referred to NHS children's services for behavioural problems. Participants will be recruited from waiting lists of NHS children's services as outlined above.

Inclusion Criteria

- The referred child is aged between three and eleven years old.
- The referred child is on a waiting list for an NHS children's service in the primary or secondary study site.

- The referred child's behavioural problems are one of the primary reasons for referral to the NHS service.
- The parent/carer identifies the referred child's behaviour as problematic.

NICE guidelines only recommend parent-focused interventions for behavioural problems with children aged between 3 and 11 years old (NICE, 2017). Child behavioural problems are an important focus of this research, hence the requirement for the referred child's behaviour to be one of the primary reasons for referral. The requirement for children to be on a waiting list for an NHS children's service means that the child and parent will be able to access treatment as usual regardless of this research and will retain an allocated lead professional from the service though the intervention. Finally, the parent/carer needs to identify the behaviour as problematic; otherwise, a guided self-help intervention would not be appropriate.

Exclusion Criteria

- The referred child has a diagnosis of developmental delay or learning disability.
- The family is current receiving active multi-agency involvement (e.g. social care, police or youth offending in addition to NHS services).
- The parent/carer is aged under 18.
- The parent/carer is unable to read or speak English fluently.

Crnic et al. (2004) state the function of behavioural problems is often different for children with a developmental delay or learning disability, making the NHA potentially unsuitable. Similarly, multi-agency involvement and parents aged under 18 years old (legally children themselves) indicate a level of need beyond what would be appropriate for a self-help intervention. The language requirement is necessary for the participants to be able to read the self-help chapters and partake in the guided self-help conversations.

Sampling

The study aims to recruit six participants and convenience sampling will be used to identify the participants.

Size of sample

Single case designs typically have between three and six participants; consensus indicates three cases is the minimum to demonstrate an experimental effect (Kratochwill et al., 2010), while more than six participants is unlikely to be feasible given the amount of data that is required from each participant in single case design research (Barlow et al., 2009)

This study aims to recruit six participants. If successful, this maximises the power of the design without compromising feasibility. If recruitment proves challenging, there is capacity to reduce numbers to three participants without invalidating the findings. Participants will be replaced if drop-out occurs during the baseline phase.

Sampling technique

Convenience sampling will be used to select the participants. Staff working in the specific services will be aware of the eligibility criteria for the study and will identify potential participants. If there are more than six parents/carers willing to participate, participants will be contacted in the chronological order by which they were identified by staff.

This will not result in a representative sample. However, this is not a problem in single case research designs (Barlow et al., 2009), as the small number of participants renders the sample unrepresentative regardless of the sampling technique. The strength of the design comes instead from the systematic and repeated measurement of specific variables (Barlow et al., 2009).

RECRUITMENT

Participants will be recruited from the treatment waiting lists of the CAMHS services. Staff working in these services will be aware of the research study and its aims; recruitment will use staff's knowledge of the families awaiting support to identify potential participants. The initial approach will be from a member of the referred child's usual care team, e.g. the allocated lead professional, who will screen potential participants who meet the study eligibility criteria (see Inclusion and Exclusion criteria above). During this initial approach, the member of the usual care team will explain the project and give the potential participant the Participant Information Sheet (PIS).

Translator services will not be used because the eligibility criteria requires participants to be fluent in written and spoken English.

The investigator or their nominee, e.g. a member of the participant's usual care team, will inform the participant or their nominated representative (other individual or other body with appropriate jurisdiction), of all aspects pertaining to participation in the study. The initial approach will be via telephone or during a scheduled appointment. If the initial approach takes place in person, such as during a scheduled appointment, appropriate Personal Protective Equipment (PPE) will be worn in accordance with the Covid-19 guidance issued by the relevant NHS Trusts. The PIS will be sent electronically (via email) or handed over in person dependant on whether the initial contact takes place in person or virtually.

Potential participants will be given a minimum of 24 hours to consider their participation before they are contacted by a member of their usual care team to give their verbal consent. If they subsequently decide to take part, the doctoral student will contact them (contact details will be passed on by the clinician who made the initial contact with the participants permission) and will be asked to sign an Informed Consent Form (ICF). The member of the usual care team who made the initial approach will also be asked to record in the referred child's clinical notes that verbal consent has been obtained for their parent/carer's contact details to be passed on to the research team. Participants will be able to sign the ICF electronically or can sign, scan and send back the form electronically. It will be explained to the potential participants that participation in the research study will not impact the treatment as usual that they receive from the service for which the referred child is on a waiting list.

It will be explained to the potential participant that entry into the trial is entirely voluntary and that their treatment and care will not be affected by their decision. It will also be explained that they can withdraw at any time, but attempts will be made to avoid this occurrence. In the event of their withdrawal, it will be explained that their data collected so far may not be erased in accordance with the University's Research Privacy Notice and information given in the Participant Information Sheet and we will seek consent to use the data in the final analyses where appropriate.

Participant Payment

Participants will not be paid to participate in the trial. There is evidence to suggest that providing a financial incentive may reduce overall intrinsic motivation to participate in research (Zutlevics, 2016). Intrinsic motivation will be important for participants' desire to learn and attempt new parenting strategies and consequently, anything that may threaten this could impact the validity of the study. Therefore, no payment will be made to participants. Participants will not incur any additional costs as a result of participating in the research.

Through participating in the intervention, participants will receive the book "Transforming the Intense Child Workbook" (Glasser, 2016) in six parts and will keep their workbook on completion of the intervention.

CONSENT

All participants shall provide written informed consent. The ICF will be signed and dated by the participant before they enter the study.

Potential participants will have been given the PIS by the member of the referred child's usual care team. Potential participants will be given a minimum of 24 hours to consider their participation before they are

contacted by a member of their usual care team to give their verbal consent for their contact details to be passed onto the research team.

The recruiting investigator (the doctoral student) will explain the details of the study and ensure participants have a PIS (and any other study related literature), making sure that the participant has sufficient time to consider participating or not. Opportunity will be given to the participant to ask any questions they may have has concerning study participation. Participants will be asked to consent to the research team accessing their child's medical record for the researcher to create a note on the child's record following each guided self-help session. It is usual practice for any clinical contact to be logged by the person making the contact, in this case the researcher, as soon after the contact as possible. By having access to the medical record, the researcher can upload the note directly after the session which is good practice and particularly important if any safeguarding issues are identified.

The process for obtaining participant informed consent will be in accordance with the REC guidance, and Good Clinical Practice (GCP) and any other regulatory requirements that might be introduced. The investigator or their nominee and the participant shall both sign and date the ICF before the person can participate in the study. Participants will be able to sign the ICF electronically or can sign, scan and send back the form electronically. One copy of the ICF will be kept by the participant, one will be kept by the research team, and a third will be retained in the referred child's medical records. It will be explained to the potential participants that participation in the research study will not impact the treatment as usual that they receive from the service for which the referred child is on a waiting list. Participants will be given the contact details of the research team should they have any further questions. Should there be any subsequent amendment to the final protocol, which might affect a participant's participation in the trial, continuing consent will be obtained using an amended consent form which will be signed by the participant. Capacity will be assumed for all participants as they will be adults (over the age of 18).

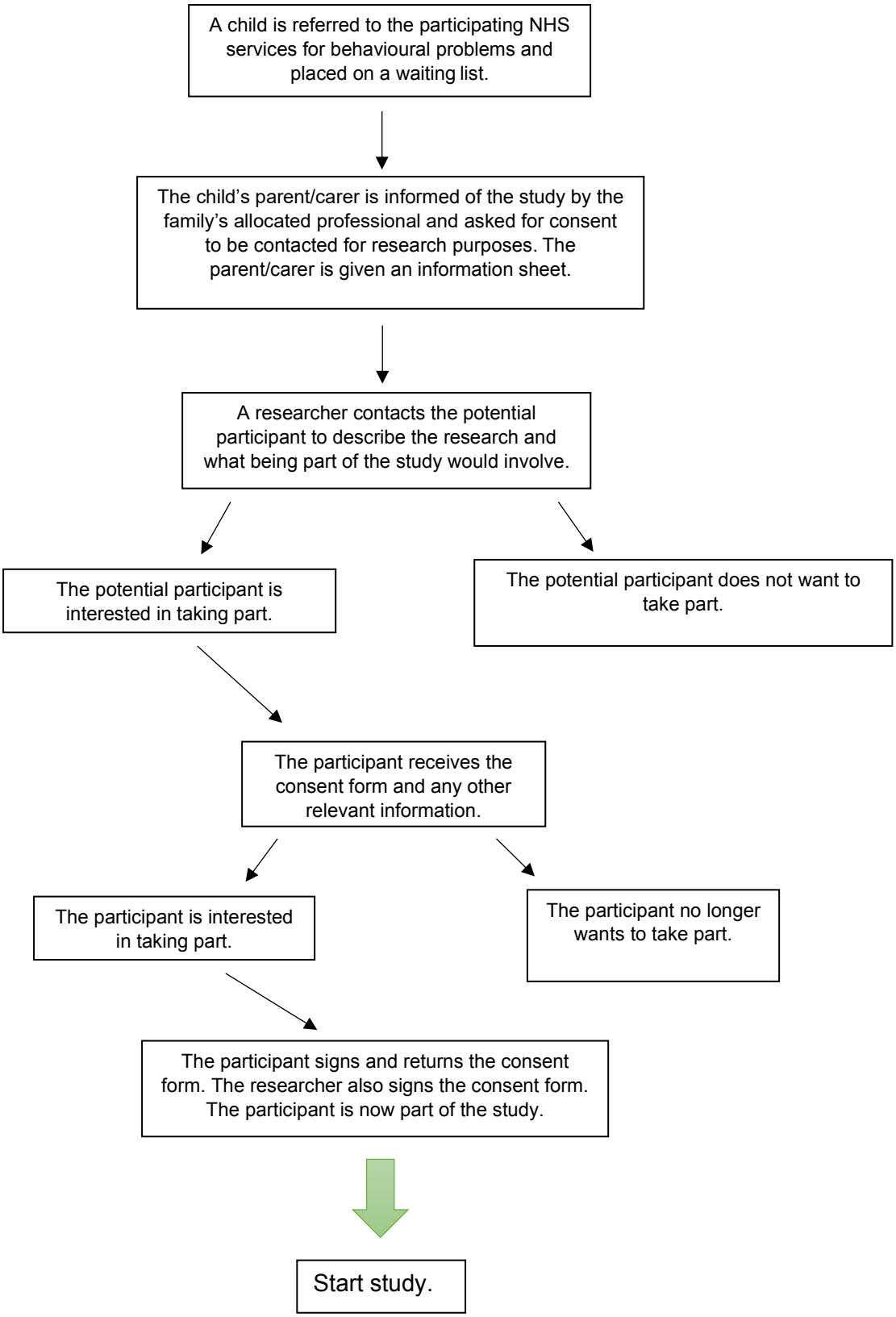
STUDY PROCEDURES/REGIMEN

STUDY FLOWCHART

Below are the study flowcharts written for the participant. The first explains the process of recruitment, the second explains participation in the intervention.

Flowchart

Recruitment.



Procedure.

Baseline Phase

The researcher contacts the participant twice per week to collect information using questionnaires (also called measures). This phase is likely to last three weeks but may be slightly longer.

- The participant decides they do not want to continue taking part in the study, informs the researcher and is withdrawn from the study.
- The participant no longer meets the eligibility criteria for the study. The researcher informs them and the participant is withdrawn from the study.
- The participant completes the baseline phase and continues to the intervention phase.

Intervention Phase

The participant will be sent one chapter of the workbook to read each week. The researcher contacts the participant once a week to collect information using questionnaires and discuss the chapter. This phase lasts six weeks.

- The participant decides they do not want to continue taking part in the study, informs the researcher and is withdrawn from the study.
- The participant no longer meets the eligibility criteria for the study. The researcher informs them and the participant is withdrawn from the study.
- The participant completes the intervention phase and continues to the follow-up phase.

Follow-up Phase

The researcher will contact the participants to complete the questionnaires for the last time and arrange a follow-up interview with an independent researcher. The follow-up interview is the participant's chance to give feedback on the intervention and how you found it.

- The participant decides they do not want to continue taking part in the studyand informs the researcher.
- After taking part in the interview, the participant has completed the study and will be sent an overview of the research unless they have opted out.

STUDY REGIMEN

The screening procedure is outlined above in the eligibility, recruitment and consent sections.

Baseline phase

Following informed consent, participants will begin the baseline phase. During the baseline phase, participants will be contacted twice a week by phone by the doctoral student to collect the data. The table below shows the frequency of administration for each measure throughout the study. The exact timing of phone calls will be organised with each participant around their availability and the availability of the doctoral student.

The necessity to complete multiple measures will be made clear to participants both in the initial conversation and PIS. If participants do not consistently complete the measures, the researcher will speak to the participant to identify why and explain the impact on the research. If measures continue not to be completed during the baseline phase, participants may be withdrawn from the study.

If stability is not achieved on any variable, participant data will be considered on a case-by-case basis. Lack of stability likely to undermine the validity of subsequent results may result in participants being withdrawn from the study. However, because each participant acts as their own control, a limited amount of variability may not have a significant impact on the study (Kratochwill et al., 2010).

Intervention phase

The intervention phase will exclusively use the official NHA self-help workbook (Glasser, 2016); a workbook will be purchased for each participant by the research team using the research budget. The doctoral student will also undertake the six-hour NHA online training course produced by the creators of the NHA (Glasser & Easley, 2016). This is to ensure that the guided aspect of the intervention is completed with as much fidelity to the approach as possible.

A chapter from the book will be sent to the participants each week through the post. Each participant will be requested to read the chapter prior to the arranged guided self-help session. The doctoral student will then contact the participant by phone to complete the guided self-help session which involves discussing the prompt questions provided in the workbook. The exact timing of phone calls will be organised with each participant based around their availability, the availability of the doctoral student and when they received the workbook in the post. Process measures will be collected at the beginning of this phone call. These sessions will be audio-recorded.

If participants do not read the chapter in advance of the phone call, the option will be given to the participant to read through the chapter jointly during the call, including prompt questions, or to postpone the phone call by a day. Flexibility will be prioritised as the time-intensive nature of the intervention is recognised. However, if participants do not attend the six intervention sessions, they will be withdrawn from the study as they will not be receiving the intervention in a standardised way.

One month post intervention, the participants will be contacted again to complete all five measures and arrange the change interview. The measures will be completed by the doctoral student. The change interview will be completed by a second doctoral student who will not previously have been involved in the study; this interview will also take place via phone and will be audio-recorded.

Frequency of measure collection

Measure	Baseline (A)						Intervention (B)												Follow-up
	Week 1		Week 2		Week 3		Week 4		Week 5		Week 6		Week 7		Week 8		Week 9		Week 13
	Day 1	Day 4	Day 1	Day 4	Day 1	Day 4	Day 1	Day 4	Day 1	Day 4	Day 1	Day 4	Day 1	Day 4	Day 1	Day 4	Day 1	Day 4	Day 1
Short Warwick-Edinburgh Mental Wellbeing Scale (SWEMWBS)	✓																	✓	✓
Psychological Outcomes Profiles (PSYCHLOPS)	✓																	✓	✓
Multidimensional Assessment of Parenting Scale (MAPS)	✓	✓	✓	✓	✓	✓		✓		✓		✓		✓		✓		✓	✓
Parental Reflective Functioning Questionnaire (PRFQ)	✓	✓	✓	✓	✓	✓		✓		✓		✓		✓		✓		✓	✓
Brief Problem Monitor (BPM)	✓	✓	✓	✓	✓	✓		✓		✓		✓		✓		✓		✓	✓

SCHEDULE OF PROCEDURES

Procedures	Sessions			
	Screening	**Baseline (weeks 1-3)**	**Intervention (weeks 4-9)**	**Follow up (week 13)**
Informed consent	x			
Demographics		x		
Measure collection		x	x	x
Intervention			x	
Change interview				x

WITHDRAWAL

Participants may be withdrawn from the trial either at their own request or at the discretion of the investigator (with input from the whole research team). The participants will be made aware that this will not affect their future care. Participants will be made aware (via the information sheet and consent form) that should they withdraw the data collected to date may not be erased in accordance with the University's Research Privacy Notice and information given in the Participant Information Sheet and may still be used in the final analysis.

Participants who withdraw prior to starting the intervention will be replaced. After starting the intervention phase, replacement of participants will be considered on a case-by-case basis depending on individual circumstances. If a participant withdraws before the start of the intervention phase, they will not receive the self-help workbook, but will be made aware that they can purchase the book themselves.

ETHICAL AND REGULATORY CONSIDERATIONS

ASSESSMENT AND MANAGEMENT OF RISK

If information is disclosed during the study that could pose a risk of harm to the participant or others, the researcher will discuss this with the CI and where appropriate report accordingly.

Risks will be managed in accordance with each trust's safeguarding policy. The Health and Care Professions Council (HCPC) practitioner psychologist guidance will also be adhered to. During participation in the study, the doctoral student may become aware of harm being caused to the referred child or other children. If a disclosure or concerns about a child are raised, the trust policies will be followed and the referred child's usual care team and the chief investigator will be informed at the earliest possible opportunity.

It is also possible that the participant will disclose that they are at risk of harm to themselves or others, or are risk of harm from others, in which case trust policies will be followed and the child's usual care team and the chief investigator will be informed at the earliest possible opportunity.

Individual participant medical information obtained as a result of this study are considered confidential and disclosure to third parties is prohibited with the exceptions noted. Medical information may be given to the participant's medical team and all appropriate medical personnel responsible for the participant's welfare.

ADVERSE EVENTS

Due to the nature of this study no adverse events are anticipated, and no adverse event data will be collected.

ETHICS REVIEW AND COMPLIANCE

The study shall not commence until the study protocol, information sheets and consent forms have been reviewed and approved from a Research Ethics Committee and relevant NHS/Social Care permission is obtained

The sponsor will be responsible for deciding whether amendments are substantial and non-substantial in collaboration with the Chief Investigator.

Where an amendment is required to study documentation that required REC approval, changes will not be implemented until REC approval and HRA categorisation is received. Where an amendment requires local approval this shall be sought prior to the amendment be implemented at each site in accordance with the categorisation given on the HRA approval letter.

Should an amendment be required to eliminate an apparent immediate hazard to participants this may be implemented immediately and the REC/HRA and R&D will be notified as soon as possible.

Minor amendments for logistical or administrative purposes may be implemented immediately

Amendments will be logged on the Sponsor's Study Amendment Log and stored in the Trial Master/Site File(s).

Annual Progress Reports shall be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given – until the end of the study.

A final report shall (where possible) be submitted to the REC within one year after the end of the study.

If the study is terminated prematurely the CI will notify the REC, including the reasons for premature termination.

PEER REVIEW

The study was reviewed as part of the academic requirements for the DClinPsy course that the doctoral student is undertaken. The feedback from the peer review by university academic staff is detailed in the scientific critique document.

PUBLIC & PATIENT INVOLVEMENT

Input will be sought by the service user and carer advisory panel (SUCAP) attached to the Trent DClinPsy programme. Initial input from SUCAP members shaped the formation of the research idea in the early stage of development (January 2021). Additionally, parents/carers have been consulted to check the readability and suitability of the participant information sheet, consent form and interview schedules.

PROTOCOL COMPLIANCE

Accidental protocol deviations may occur at any time. Accidental protocol deviations will be adequately documented on the relevant forms and reported to the Chief Investigator and Sponsor immediately.

Deviations from the protocol which are found to frequently recur are not acceptable, these will require immediate action and could potentially be classified as a serious breach.

DATA PROTECTION AND PATIENT CONFIDENTIALITY

All study staff and investigators will comply with the principles of the General Data Protection Regulation (GDPR) 2016/079 in protecting the rights of study participants with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's/Regulations core principles.

Each participant will be assigned a participant identification code, for use on study records, other study related documents and the electronic database. Personal data, as defined under the Data Protection Act, will include participant demographics, contact details, signed consent forms, recordings of intervention sessions and

recordings and transcripts of change interviews. Completed measures will not be personally identifiable as an anonymised participant identification code will be used.

Personal data, research data and the linking code will be stored in separate locations. When stored electronically, this will include using encrypted digital files within password protected folders and storage media. Personal information shall be stored separately to research data and will be kept secure, and maintained.

All electronic data will be uploaded on a dedicated secure University of Lincoln web server which uses two factor authentication; access will be restricted by user identifiers and passwords. Paper-based data will be kept in a locked filing cabinet at the University of Lincoln; this will include all data except audio recordings. These recordings will be kept on a password-protected encrypted USB memory stick that will be kept in a locked draw when not being used. When uploaded to the University of Lincoln server, the original audio files will be deleted from the USB. Administrative staff on the Trent DClinPsy will have access to the filing cabinets, but hard copy data will be kept in sealed envelopes. Access to the information will be limited to the study investigators and relevant regulatory authorities. Data analysis will use anonymised data and all data files will be password protected and saved on University of Lincoln servers, which require two-factor authentication. Participants will be given pseudonyms in the write up of the research and any identifiable details will be changed.

Personal data will be stored for 6 months following the end of the study, so that the Chief Investigator may provide participants with a summary of the research (should they wish to receive a copy).

All study data will be stored for 5 years following the end of the study, so that the Chief Investigator may provide participants with a summary of the research (should they wish to receive a copy).

Data generated as a result of this study will be available for inspection on request by the participating physicians, the University of Lincoln representatives, the REC, local R&D Departments and the regulatory authorities.

INDEMNITY

Insurance and indemnity for trial participants and trial staff is covered within the NHS Indemnity Arrangements for clinical negligence claims in the NHS, issued under cover of HSG (96)48. There are no special compensation arrangements, but trial participants may have recourse through the NHS complaints procedures.

The University of Lincoln as research Sponsor indemnifies its staff, research participants and research protocols with both public liability insurance and clinical trials insurance.

ACCESS TO THE FINAL DATASET

The full study documentation and data will be restricted to staff on the research team. The anonymised quantitative dataset may be uploaded and stored on the open access University of Lincoln Repository (ePrints). All documents shall made be available at all times for review by the Chief Investigator, Sponsor's designee and inspection by relevant regulatory authorities.

DISSEMINATION POLICY

The data custodian will be the Chief Investigator on behalf of the University of Lincoln.

This research will be submitted in partial fulfilment of the requirements of the Trent Doctorate in Clinical Psychology. It is the intention to submit the research to a peer-review journal to allow for wider readership. The findings may be disseminated through relevant conferences. Participants will receive a summary of the findings, unless they have opted out on the consent form. All data disseminated will be anonymised.

The total expected duration of the study is 13 months. Planned start date: February 2022 (dependant on approval by ethics committee). Planned thesis submission date: February 2023.

Authorship eligibility guidelines and any intended use of professional writers

The doctoral student will be the primary author on all publications related to this project. The chief investigator and all co-investigators will be co-authors and authorship will be decided based on contribution at the time of publication.

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