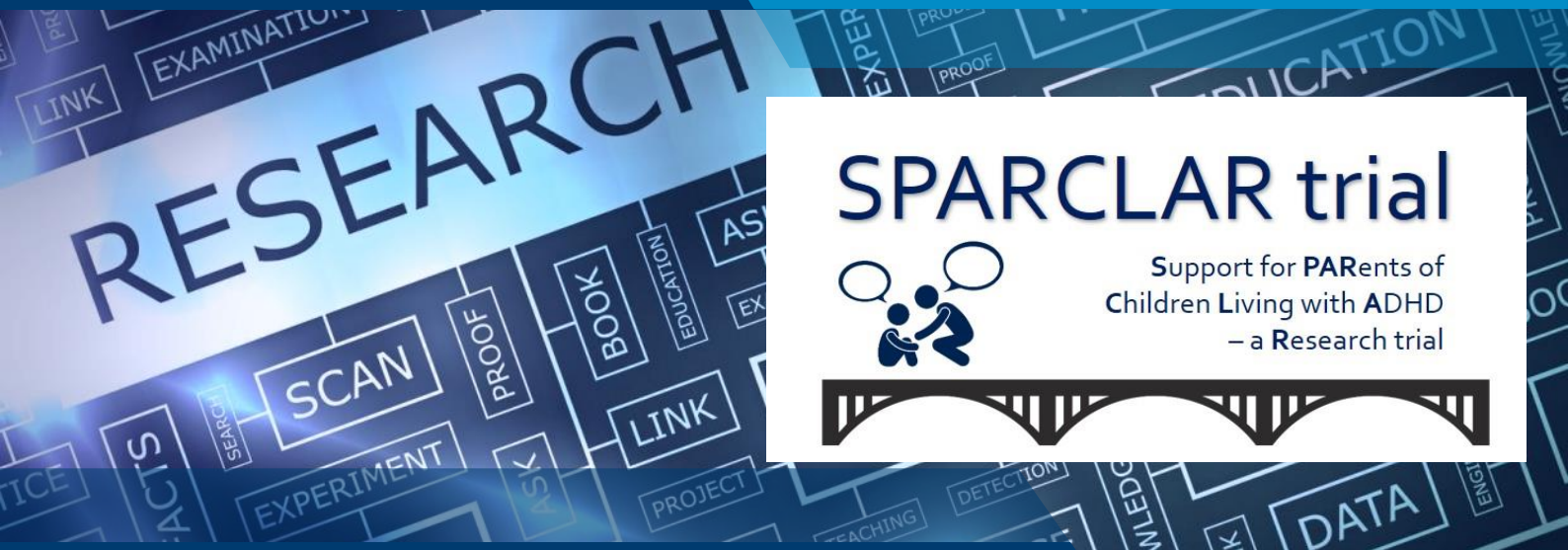
CHIEF SCIENTIST OFFICE

CODE: HIPS/17/58

RESEARCH PROJECT BRIEFING



Support for PARents of Children Living with ADHD (SPARCLAR) – a feasibility randomised controlled trial

AIMS

Our main aim was to examine the feasibility of a future definitive randomised controlled trial (RCT) to compare two parenting programmes for families of school-aged children with ADHD (Attention Deficit / Hyperactivity Disorder): Parents InC (PInC) and Incredible Years (IY).

PInC is a 6-week (2 hrs per week) group-based programme specifically for parents of children diagnosed with ADHD. It offers specific support around empowerment, information and behaviour management specific to ADHD, as well as understanding of the child's development context. IY is a 14-week (2-3hrs) group parenting support intervention aimed at strengthening parent-child interactions and attachment, reducing harsh discipline and fostering parents' ability to promote children's social, emotional, and academic development. Clinical Trials reg no. NCT03832270.

KEY FINDINGS

- We **recruited** 30/52 (**58%**) of eligible participants (14 randomised to PInC, 16 to IY). **Retention rates** were very high: 22 of the 30 participants (**73%**) provided follow-up quantitative data and 24 (80%) participated in qualitative interviews.
- Parents randomised to PInC had a slightly **better sense of parenting competence**, at 12 month follow-up, compared to those randomised to IY, although **groups were not completely balanced** in terms of parental ADHD scores and deprivation.
- Participant **feedback on research procedures and methods was positive**, and qualitative interviews provided a rich source of learning points to take forward into a future definitive trial. Key points were the **importance of researchers adopting a flexible approach** to data collection, including being open to making **multiple contacts**. Waiting times for groups occasionally resulted in participants switching to the other intervention – a future trial will need to include consideration of this possibility in sample size planning.

WHAT DID THE STUDY INVOLVE?

This was a feasibility randomised controlled pilot trial comparing two parenting programmes for families of children aged 5-12 years with ADHD. A randomised controlled trial, or RCT, is a research design that allows us to say confidently whether any change in primary outcome measure has happened as a result of participation in an intervention. This is because each participant has an equal chance of receiving the intervention, and with a large enough sample we can be confident that the groups receiving and not receiving the intervention will have similar characteristics and that the study is 'powered' to detect a meaningful difference in outcome measure.

Participants were recruited from the NHS Fife integrated ADHD pathway. Primary feasibility measures were recruitment and retention rates, and our primary outcome measure, which we would be likely to use in a future definitive trial, was the Parenting Sense of Competence scale (PSOC). PSOC is a validated and widely used questionnaire measure which asks parents to rate their level of agreement with a list of 17 statements regarding their feelings about their parenting self-confidence.

We also measured children's behaviour and wellbeing, parents' wellbeing, parenting-related stress, and ADHD symptoms, parents' goals for intervention, quality of life and health service use (all parent-report questionnaires). All measures took place at baseline and follow-up (12 months after randomisation for most, 6 months post-randomisation for the final 5 participants entered into the study).

Semi-structured interviews with participants and professionals assessed the acceptability of research procedures at two time points – during the intervention period (T1), and at 12 / 6 month follow-up (T2). Our trial steering committee included two parents of children with ADHD who helped shape our research materials and advised on study design and dissemination. The impact of the pandemic was minimal as intervention was complete and remote assessments were successful.

WHAT WERE THE RESULTS AND WHAT DO THEY MEAN?

Recruitment & Retention

Overall, recruitment and retention rates were good (see Fig 1 on the next page for details). Reasons for non-participation were understood and learning can be applied to a future definitive trial (see below). There were some differences in the sample characteristics between the two arms at baseline: we would expect this to be mitigated by a larger sample size in future.

Qualitative interviews – key themes

- Researcher approach: empathic interactions and flexibility of data collection methods
- Study information: study was well explained and facilitated by the research team
- Timing of intervention: waiting for the next available group to start led to some drop-out
- School: home-schooling during the pandemic was more challenging for this group.

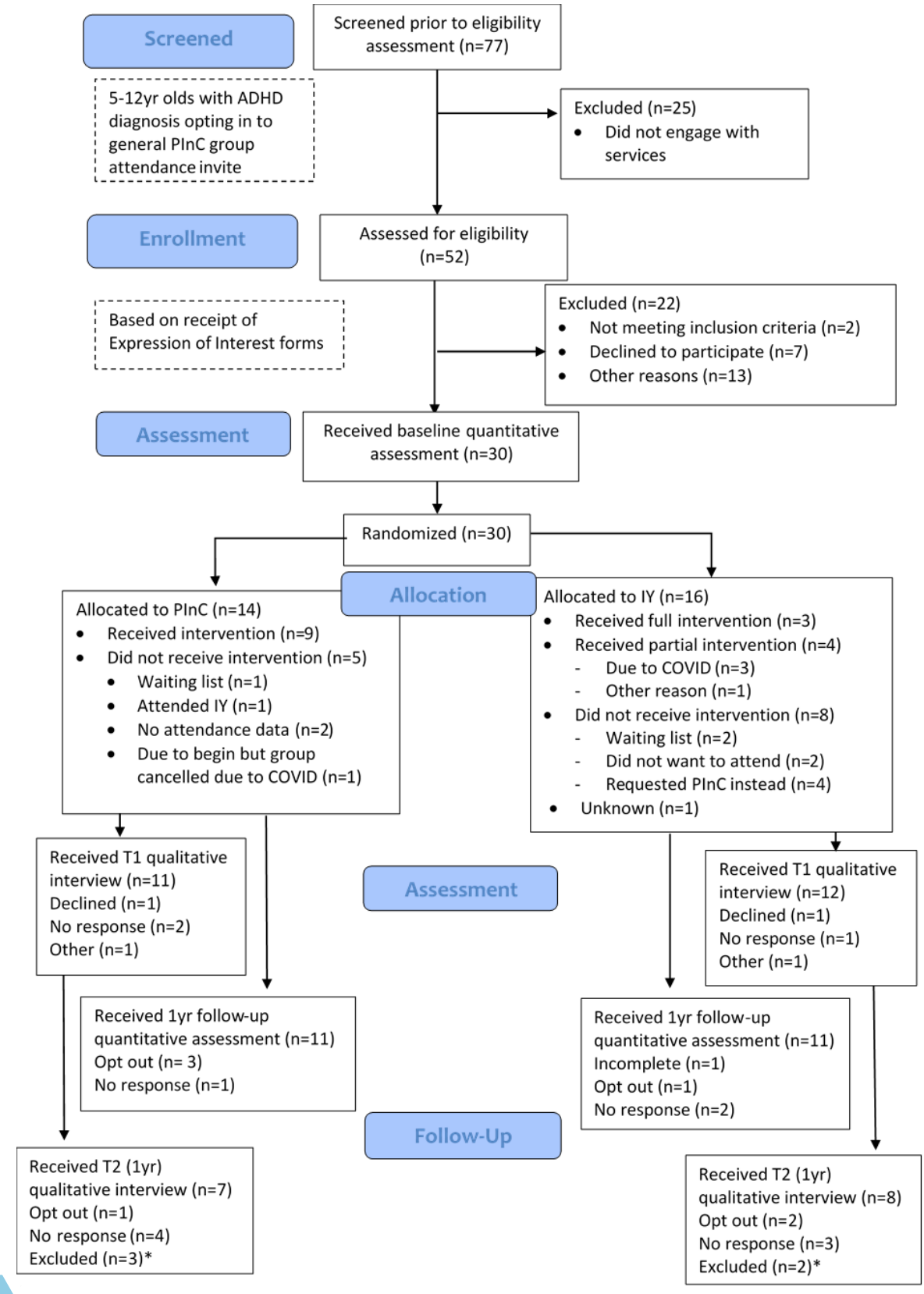
Process evaluation

- Average of 3 contact attempts per participant to obtain baseline data, 7 for follow-up.
- Recognise need to have recruiters 'on the ground' in service context.

Outcomes

- PInC group scored better than IY group on PSOC, but sample small & unbalanced, so unreliable.
- Statistical power for a definitive trial: we would need to have follow-up data on 86 participants per arm. Based on our recruitment and follow-up rates, we would need to recruit around 230 participants to reach this figure.
- Costs per group: £14,957 PInC; £26,489 IY. Associated health service costs: IY participants had more outpatient visits in 12 months post-randomisation, but use of other services was similar across arms.

Figure 1: CONSORT flow diagram



WHAT IMPACT COULD THE FINDINGS HAVE?

A definitive trial comparing Parents InC and Incredible Years is feasible.

- A definitive trial, with sufficient power to assess effectiveness of the interventions, could be planned for the near future.
- Any future trial should adopt a researcher-led recruitment strategy, incorporate additional outcome measures, and monitor intervention group progress more closely.
- If PInC is demonstrated to be at least as effective as IY, there are significant implications for reducing the cost of interventions and the time investment from families.

HOW WILL THE OUTCOMES BE DISSEMINATED?

This study has been written up for publication in a peer-reviewed scientific journal.

A second paper focusing on families' experiences as expressed in the qualitative interviews is under preparation, also for submission to a peer-reviewed scientific journal.

We plan to present the findings at an international conference, once opportunities open up (post-pandemic).

We shall continue to work with our stakeholders, including parents, practitioners, and researchers from different disciplines, to use the learning from the present study to plan a definitive trial in the near future (a funding application to be submitted this year).

CONCLUSION

A definitive trial comparing Parents InC and Incredible Years is feasible. Recruitment to the feasibility trial was acceptable and retention very high. Changes in the primary outcome measure at follow-up suggest a larger, definitive, RCT might favour Parents InC.

A definitive trial should adopt a researcher-led (rather than service-led) recruitment strategy and closely monitor intervention group progress.

RESEARCH TEAM & CONTACT

Dr Lucy Thompson & Prof Helen Minnis

University of Glasgow, Institute of Health and Wellbeing, 1 Horselethill Road, Glasgow G12 9LX

Lucy.Thompson@glasgow.ac.uk
Helen.Minnis@glasgow.ac.uk

0141 201 9239

Additional Information

Data collection completed in February 2021, with project ending November 2021

Funding received £277,621