ISRCTN71988966 https://doi.org/10.1186/ISRCTN71988966

A parenting programme for Japanese mothers of children at risk of attention deficit hyperactivity disorder (ADHD)

Submission date
29/05/2015

Recruitment status
No longer recruiting

Registration date
15/06/2015

Overall study status
Completed

Last Edited
18/11/2021

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Attention deficit hyperactivity disorder (ADHD) is a neurodevelopmental disorder characterised by elevated levels of inattentive, hyperactive and impulsive behaviours. Children with ADHD have difficulty taking turns, are frequently forgetful, talk excessively, often appear not to be listening when spoken to, and tend to interrupt and intrude on others in group activities, conversations and classroom discussions. Parenting a child with ADHD is especially demanding. Parents of children with ADHD report elevated levels of parenting stress and depression, which impacts negatively on their parenting practices. Interactions between parents and children with ADHD have been shown to be more negative and controlling than those of parents of typically developing children. Furthermore, mothers' experiencing high levels of distress often lack the motivation or organisational skills to parent their child in a consistent way. Addressing the psychological needs of parents' of children with ADHD would seem, therefore, to be an important treatment target together with strategies to manage the children's symptoms of ADHD. However, the majority of available programmes focus on teaching behaviour modification /parenting skills to parents. To date only a small number of studies have directly targeted the psychological difficulties parents of children with ADHD face. Group-based programmes for parents of children with behaviour problems, including ADHD, have been shown to result in positive changes in mother's perceptions of their child's behaviour. However, most group-based treatments report minimal effect on the core symptoms of ADHD as they target the parental management of overt oppositional behaviours rather than the impairments underlying ADHD in the child. The New Forest Parenting Program (NFPP) was developed specifically for children with ADHD, targeting the core symptoms of the disorder including attention, impulse control, and self-organisation. The aim of this study is to see how well a modified parenting programme incorporating the NFPP works to reduce mothers' stress and help them to manage their child's ADHD behaviour.

Who can participate?
Japanese mothers of children with symptoms of ADHD aged 6-12.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 (intervention group) take part in 13 two-hour sessions of a group parent training programme for Japanese mothers of children with ADHD aged 6 to 12 (5 sessions of parent stress reduction and 8 sessions of the NFPP). Those in group 2 (control group) are put on a waitlist and are given access to the same group parent training programme as the intervention group once the other group have completed the sessions. All participants are asked to complete questionnaires.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
Okinawa Institute of Science and Technology Graduate University (Japan)

When is the study starting and how long is it expected to run for?
September 2014 to July 2017

Who is funding the study?
1. Okinawa Institute of Science and Technology Graduate University (Japan)
2. Japan Society for the Promotion of Science (KAKENHI) (Japan)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HSR-2014-005

Study information

Scientific Title
Randomised controlled trial of a modified version of the New Forest Parenting Programme for Japanese mothers of children at risk of attention deficit hyperactivity disorder (ADHD)

Study objectives
1. The intervention will be associated with a great reduction in parenting stress relative to the wait-list control group
2. The intervention will be associated with greater enhancement of parenting skills relative to the wait-list control group
3. The intervention group will display greater reduction of behaviour problems (ADHD and conduct problems) relative to the wait-list control group

Ethics approval required
Old ethics approval format

Ethics approval(s)
Okinawa Institute of Science and Technology Graduate University Institutional Review Board, 01 /08/2014. , ref: HSR-2014-005

Study design
Two-arm randomised control trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Attention deficit hyperactivity disorder (ADHD)

Interventions

This is small-scale randomised controlled trial to assess the efficacy of New Forest Parenting Program-Japan (NFPP-J) when compared to a wait list control group. The trial will have one treatment arm: a group receiving NFPP-J and a wait list control group who will be offered NFPP-J at the end of the trial.

Arm 1: Mothers are invited to take part in a thirteen-session group parenting program that incorporates 5 sessions of psycho-education (knowledge of ADHD, stress management and relaxation, cognitive restructuring, problem solving skills, effective communication skills) and 8 sessions of New Forest Parenting Program (NFPP).

Arm 2: Wait-list control mothers accepting offer of treatment complete program as described for Arm 1.

When sufficient participants meeting inclusion criteria are recruited they will be randomised to a study arm using a simple randomisation procedure based on a computer random number generator. Time 1 outcome measures will be obtained from parents and teachers, including the FMSS and the parent-child interaction task prior to randomisation to study arm.

Intervention Type
Behavioural

Primary outcome measure
Parental self report on the parenting stress index short form at baseline and 14 weeks.

Secondary outcome measures
1. Self reported parenting practices on the parenting scale and objective parenting measured via structured observations of parent-child interaction at baseline and 14 weeks
2. Parent and teacher reports of ADHD symptoms on the Swanson Nolan and Pelham scale (SNAP) at baseline and 14 weeks
3. Internalising and externalising problems as measured by parental report on the Child Behavior Checklist (CBCL) at baseline and 14 weeks

Overall study start date
20/09/2014

Completion date
30/07/2017

Eligibility

Key inclusion criteria
Children at risk of ADHD aged 6-12 and their mothers. Children at risk of ADHD are identified through a three stage process:
1. Parental concern about child's ADHD behaviours
2. Child's score above the point of clinical concern on the parent SNAP
3. Parent willing to engage in behavioral intervention

Participant type(s)
Patient

Age group

Mixed

Sex
Both

Target number of participants
60 parent-child dyads

Total final enrolment
104

Key exclusion criteria
1. Primary diagnosis of ASD
2. Families where the father is the primary caregiver
3. Japanese is not first language
4. Severe maternal mental illness

Date of first enrolment
01/07/2014

Date of final enrolment
30/01/2017

Locations

Countries of recruitment
Japan

Study participating centre
Okinawa Institute of Science and Technology Graduate University
7542 Onna
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Sponsor information

Organisation
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Sponsor type
University/education

ROR
https://ror.org/02qg15b79

Funder(s)

Funder type
Other

Funder Name
Okinawa Institute of Science and Technology Graduate University (Japan)

Funder Name
Japan Society for the Promotion of Science (KAKENHI) (Japan)

Results and Publications

Publication and dissemination plan
Irrespective of the trial outcome the results of the trial will be submitted for publication in an international peer reviewed journal.

Intention to publish date
01/03/2017

Individual participant data (IPD) sharing plan
Data will not be shared because neither the ethics application nor consent forms included the statement that the raw data and/or anonymized data will be made available. Data from this randomized control trial is not expected to be made available.

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		03/03/2020	18/11/2021	Yes	No