

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

<b>Submission date</b> 29/05/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 15/06/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 18/11/2021	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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?

Dr S Shimabukuro

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## Contact information

**Type(s)**

Scientific

**Contact name**

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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

Onna-son Okinawa

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## **Sponsor information**

**Organisation**

Okinawa Institute of Science and Technology Graduate Univers

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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?
<a href="#">Results article</a>		03/03/2020	18/11/2021	Yes	No