ISRCTN66978270 https://doi.org/10.1186/ISRCTN66978270

The training and nurturing support for mothers study

Submission date
04/02/2020

Recruitment status
No longer recruiting

Registration date
16/03/2020

Overall study status
Completed

Last Edited
24/04/2023

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Attention deficit hyperactivity disorder (ADHD) is characterised by higher 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 Parent Stress Management Programme was also specifically developed to target parental well-being of parents of children with ADHD. Well Parent Japan is a modified hybrid programme which contains information and education about ADHD, four sessions from the Parent Stress Management Programme targeting both stress and mood difficulties and a culturally adapted Japanese version of the New Forest Parenting Programme. The Well Parent Japan intervention has been evaluated in a small scale study and has been shown to be helpful at reducing child symptoms and behaviours, enhancing parental well-being and parenting practices immediately after the end of the intervention.
The aim of this study is to extend the results of this small scale trial to a much larger trial run at three different hospitals in Japan, evaluating the Well Parent Japan intervention in routine

ADHD clinics and comparing it to treatment as usual (what those clinics usually offer). The study will also aim to evaluate the intervention both immediately after mothers have received it, but also at a three-month follow-up to explore the impact of Well Parent Japan on child behaviour, symptoms, impairment and impact on the family, parental well-being, parenting practice and maternal emotional relationships. There will also be an economic evaluation to establish how much it costs to delivery Well Parent Japan in routine Japanese health care settings, and to also determine how cost-effective the intervention is.

Who can participate?
Japanese mothers of children with a diagnosis of ADHD aged 6-12, whose children are associated with the hospital clinics at the three study sites (Fukui University Hospital, Fukui, Japan Kurume University Hospital, Fukuoka, Japan and Ryukyu University Hospital, Okinawa, Japan

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 (treatment as usual) will continue to receive whatever is offered by their hospital clinic. All participants are asked to complete questionnaires at all three timepoints and also take part in observations while helping their child to make pasta and a short interview where they describe their child and how they get along with them at time one and two only. Mothers in the treatment as usual arm of the study will be offered the Well Parent Japan intervention at the end of the study and complete a fourth set of questionnaires after completion of the intervention to increase the number of parents available for the analysis to determine which type of children and mothers respond best to Well Parent Japan.

What are the possible benefits and risks of taking part?
Mothers can gain skills to improve their parenting practices and strategies to help them to help their child. There are no identified risks of participating.

Where is the study run from?
1. Okinawa Institute of Science and Technology Graduate University (Japan)
2. University of Fukui Hospital (Japan)
3. Kurume University Hospital (Japan)
4. National Hospital Organization Ryukyu Hospital (Japan)

When is the study starting and how long is it expected to run for?
August 2018 to March 2022

Who is funding the study?
Okinawa Institute of Science and Technology Graduate University (Japan)

Who is the main contact?
Dr S Shimabukuro
shizuka.shimabukuro@oist.jp

Contact information

Type(s)
Public

Contact name
Dr Shizuka Shimsbukuro

ORCID ID
http://orcid.org/0000-0003-2899-2788

Contact details
Okinawa Institute of Science and Technology Graduate University
Onna-son
Japan
904-0495
+81 (0)98 966 8814
shizuka.shimabukuro@oist.jp

Type(s)
Scientific

Contact name
Dr Shizuka Shimabukuro

ORCID ID
http://orcid.org/0000-0003-2899-2788

Contact details
Okinawa Institute of Science and Technology Graduate University (Japan)
Onna-son
Japan
904-0495
+81 (0)98 966 8814
shizuka.shimabukuro@oist.jp

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
HSR-2019-014

Study information

Scientific Title

A pragmatic randomised controlled cost-effectiveness study of Well Parent Japan for Japanese mothers of children with Attention Deficit Hyperactivity Disorder (ADHD): the TRaining And Nurturing Support FOR Mothers (TRANSFORM) study

Acronym
TRANSFORM

Study objectives
1. That Well Parent Japan (WPJ) will be superior to Treatment As Usual (TAU) on measures of child behaviour, parental well-being and parental and objective measure of parenting
2. That Well Parent Japan will be more cost-effective than Treatment As Usual based on ADHD symptom reduction using incremental cost-effectiveness ratios (ICER)
3. That there will be no significant exploratory predictors of Well Parent Japan treatment outcome

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/12/2019, Okinawa Institute of Science and Technology Graduate School Human Subject Research Review Committee (Occupational Health and Safety Section, Human Subject Research Review Committee, Lab 1, B051, 1919-1 Tancha, Onna-son, Kunigami-gun Okinawa, Japan 904-0495; Tel: +81 (0)98 966 2385; Email: research_oist.jp), ref: HSR-2019-014

Study design
Two-arm pragmatic randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format

Health condition(s) or problem(s) studied
Attention Deficit Hyperactivity Disorder (ADHD)

Interventions
Well Parent Japan is a 13-session group-based intervention for parents of children with ADHD. The program includes an orientation to the intervention and psycho-education about ADHD, four sessions devoted to enhancing mothers psychological functioning based on Parent Stress Management for ADHD developed by Tracy Tripp & Baird (2005) followed by the eight sessions

of behaviour management based on a Japanese cultural adaption of the core components of the New Forest Parenting Programme (Sonuga-barke et al 2001; Shimabukuro et al 2017; Shimabukuro et al 2020).

Participants are randomly allocated into one of two groups. The method of randomization is at the individual level using a random number generator at the University of Nottingham. 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 (treatment as usual) will continue to receive whatever is offered by their hospital clinic. All participants are asked to complete questionnaires at all three timepoints and also take part in observations while helping their child to make pasta and a short interview where they describe their child and how they get along with them at time one and two only. Mothers in the treatment as usual arm of the study will be offered the Well Parent Japan intervention at the end of the study and complete a fourth set of questionnaires after completion of the intervention to increase the number of parents available for the analysis to determine which type of children and mothers respond best to Well Parent Japan. The total duration of follow up is 13 weeks post-intervention 26 weeks after the start of the intervention.

Intervention Type
Behavioural

Primary outcome measure
Parent stress measured by the Parent Stress Index (PSI) at T1, T2 and T3 for intervention group and T1, T2, T3, T4 and T5 for TAU group as TAU also receive intervention at the end of TAU to inform the predictors of outcome analysis

T1: baseline, T2: 14 weeks, T3: 26 weeks, T4: 39 weeks, T5: 51 weeks

Secondary outcome measures
1. Parenting style measured by the Parenting Scale at T1, T2 and T3 for intervention group and T1, T2, T3, T4 and T5 for TAU group as TAU also receive intervention at the end of TAU to inform the predictors of outcome analysis
2. Parenting competence/efficacy measured by the Parenting Sense of Competence Scale (PSOC) at T1, T2 and T3 for intervention group and T1, T2, T3, T4 and T5 for TAU group as TAU also receive intervention at the end of TAU to inform the predictors of outcome analysis
3. Locus of control assessed using the Parental Locus of Control Scale (PLOC) at T1, T2 and T3 for intervention group and T1, T2, T3, T4 and T5 for TAU group as TAU also receive intervention at the end of TAU to inform the predictors of outcome analysis
4. Mother’s mood measured by BDI-2 at T1, T2 and T3 for intervention group and T1, T2, T3, T4 and T5 for TAU group as TAU also receive intervention at the end of TAU to inform the predictors of outcome analysis
5. Child’s ADHD symptoms measured by mother and teacher by the Swanson, Nolan & Pelham Scale SNAP at T1, T2 and T3 for intervention group and T1, T2, T3, T4 and T5 for TAU group as TAU also receive intervention at the end of TAU to inform the predictors of outcome analysis
6. Parent/caregiver and teacher perceptions of emotional and behavioural problems in children measured by the Child Behavior Check List (CBCL) and Teacher Rating Form (TRF) at T1, T2 and T3 for intervention group and T1, T2, T3, T4 and T5 for TAU group as TAU also receive intervention at the end of TAU to inform the predictors of outcome analysis
7. Child’s impairment in school performance and relationship measured by mother and teacher by the performance scale from the Vanderbilt Assessment Scale at T1, T2 and T3 for

intervention group and T1, T2, T3, T4 and T5 for TAU group as TAU also receive intervention at the end of TAU to inform the predictors of outcome analysis
8. Child's impairment in eight different domains of functioning measured by the Impairment Rating Scale at T1, T2 and T3 for intervention group and T1, T2, T3, T4 and T5 for TAU group as TAU also receive intervention at the end of TAU to inform the predictors of outcome analysis
9. Family stress, strain and burden measured by the Family Strain Index (FSI) T1, T2 and T3 for intervention group and T1, T2, T3, T4 and T5 for TAU group as TAU also receive intervention at the end of TAU to inform the predictors of outcome analysis
10. Mother-child interaction assessed by direct observation of behavior during a co-operative pasta-making task. Mother and child will be video-recorded and coded by an independent coder. Interactions will be coded using codes from the System for Coding Interactions and Family Functioning (SCIFF) and the System for Coding Interactions in Parent-Child Dyads (SCIPD) at T1 and T2
11. Mother's expressed emotion measured by using the Revised Five-minute Speech Sample (R-FMSS) at T1 and T2
12. Cost-effectiveness of this study measured by the modified Client Service Receipt Inventory (CSRI) at T1 T2 and T3
13. Autism Spectrum Disorder (ASD) measured using the Autism Spectrum Quotient at baseline only at T1
4. Mother's ADHD measured by the Conners Adult ADHD Rating Scale (CAARS) at baseline only at T1

T1: baseline, T2: 14 weeks, T3: 26 weeks, T4: 39 weeks, T5: 51 weeks

Overall study start date
30/08/2018

Completion date
31/03/2022

Eligibility

Key inclusion criteria
Mothers of children diagnosed with ADHD and the children themselves will be identified by health professionals working in hospitals or community clinics linked to the three research sites in Japan. Inclusion criteria for mothers will be:
1. Fluency in Japanese (reading and writing)
2. Parenting a child, 6-12 years who is diagnosed with ADHD
3. Participation in a behavioural intervention for the mother is not contra-indicated as viewed by the referring clinician

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants

120

Key exclusion criteria
1. Children with very little pragmatic speech as judged by the referring clinician
2. Children with functional intellectual disability
3. Mothers who are currently or have recently taken part in other parenting intervention (within two months)

Date of first enrolment
13/08/2019

Date of final enrolment
30/04/2021

Locations

Countries of recruitment
Japan

Study participating centre
University of Fukui Hospital
23-3 Matsuokashimoaizuki Eiheiji Yoshida District
Fukui
Japan
910-1193

Study participating centre
Kurume University Hospital
67 Asahimachi Kurume
Fukuoka
Japan
830-0011

Study participating centre
National Hospital Organization Ryukyu Hospital
Kin 7958-1 Aza Kin-cho, Kunigami-gun
Okinawa
Japan
904-1201

Sponsor information

Organisation
Okinawa Institute of Science and Technology Graduate University

Sponsor details
1919-1 Tancha Onna-son, Kunigami-gun
Okinawa
Japan
904-0495
+81 (0)98 966 1512
grants@oist.jp

Sponsor type
University/education

Website
http://www.oist.jp/

ROR
https://ror.org/02qg15b79

Funder(s)

Funder type
University/education

Funder Name
Okinawa Institute of Science and Technology Graduate University

Alternative Name(s)
Okinawa Institute of Science and Technology, OIST

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Japan

Results and Publications

Publication and dissemination plan

Study protocol manuscript to be submitted. The intention is to publish one main trial outcome paper which will contain both the immediate and longer term effectiveness and cost effectiveness data and a second paper which will report the exploratory predictors of outcome.

Intention to publish date
01/04/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made publicly available but individual requests for access to the data will be considered subject to Japanese law.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		19/04/2022	20/04/2022	Yes	No
Statistical Analysis Plan		02/06/2022	24/04/2023	No	No