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Evaluation of the ABC - a parental support program

Submission date	Recruitment status	[_] Prospectively registered
19/10/2012	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/11/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
21/05/2024	Other	

Plain English Summary
Background and study aims
Parents and family are essential for a child's development and well-being. Since the trajectory of an individual's mental health begins in childhood, it is of importance to reach parents in efforts to promote children's positive development. The program in this trial, the ABC program, is a structured health-promoting universal parent program that targets parents of children aged 3-12 years. The program aims for increasing parental competence as well as children's development and well-being by strengthening the relationship between parents and their children. The overall aim of this trial is to evaluate the effects and the implementation of the ABC program.

Who can participate?
Parents were informed of the opportunity to participate in an ABC parent group within the study by information given in child health centres, family centres, Social Services Offices, in parent meetings at schools, primary schools and preschools, but also by adverts in local newspapers, magazines targeted towards parents, and adverts on different web sites.

What does the study involve?
Families are randomly assigned to either the intervention group or to a 6-month waiting list control group. The intervention group participates in the ABC program while the 6-month waiting list control group will not receive any parental intervention or other family treatment during the waiting list period, but will receive the program after 6 months. The ABC program comprises four parent group sessions, which are held every other week during an 8-week period, with an optional booster session after the 6-month follow-up. At the sessions the parents discuss how to obtain or develop certain parental skills, which they are supposed to practice at home with their child. Parents get information and support in how to enhance parental competence and positive child development. The method consists of four sessions with the themes 'showing love', 'being together', 'guiding' and 'pick your battles'. Sessions are led by two trained group leaders with various backgrounds such as pre-school teachers, teachers, counsellors and psychologists. Participants complete questionnaires before the intervention, immediately after the intervention as well as six and twelve months after the start of the

intervention. Parents rate their own mental health and parenting practices, as well as the child's mental and physical health and relationships with their parents and peers. The control group also answers the questionnaires at the same time, except for the 12-month follow-up.

What are the possible benefits and risks of participating?
The benefits of participation in this study are that parents participate in a program that is implemented in schools' and pre-schools' ordinary work. The risk of participation in this study is that the program turns out to be not effective in the described outcomes.

Where is the study run from?
The County of Stockholm (Sweden).

When is the study starting and how long is it expected to run for?
The study will run from February 2012 to June 2014.

Who is funding the study?
Swedish National Institute of Public Health (Sweden).

Who is the main contact?
Lene Lindberg
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Study website
http://www.allabarnicentrum.se

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title
Universal parental support program for increasing parental efficacy, children's mental health and well-being - a randomized controlled trial

Acronym
ABC-RCT

Study hypothesis
1. Parents' own experiences of parental efficacy will increase at follow-up in the intervention group, compared to the control group
2. The parents in the intervention group will report higher levels of mental health and well-being for their children at post intervention period, and at six-month follow-up, compared to parents in the control group
3. The expected effects are moderated by parent's country of birth, socio-economic status such as income and level of education, levels of program fidelity of group leaders, and parents commitment to the ABC-method and to the group meetings
4. The expected effects are mediated by parents' retaining of family rules, positive and negative reinforcement, parents' mental health and emotion regulation
5. Intervention will improve the parenting, which is moderated by strengthening the parents' relationship and well-being. These improvements affect their children's positive development
6. A health economic evaluation of the ABC-program will demonstrate savings and health gains

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Review Board at the Karolinska Institutet, 16/02/2012, ref: 2012/93-31/5

Study design
Clustered multi-centre randomization design

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet [Swedish]

Condition
Development of child mental and physical health

Interventions
Intervention group receives parental support consisting of the ABC-method, where the program format comprises four parent group sessions which are held every other week during an eight week period, with an optional booster session after two-three months. At the sessions the parents discuss and reflect on certain parental skills which they are encouraged to practice at home with the child. Parents get information and support in how to strengthen already existing promotive factors within the family in order to enhance the positive child development. The program format consists of four sessions with the themes; 'showing love'; 'being together'; 'guiding' and 'pick your battles'. Sessions are led by two trained group leaders with various backgrounds such as pre-school teachers, teachers, social workers and psychologists. The leader education consists of four and a half days of lectures and training under supervision.The 6-month wait-list control group will not receive any parental intervention or other family treatment during the waiting list period.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Time points of primary interest for all outcome measures are at baseline, two weeks after intervention period and six months after intervention start.

Parental Self-Efficacy (PSE) to measure parents' perception of their parenting on a 48-item questionnaire rated on 11-point Likert scale, ranging from 0=completely disagree to 10= completely agree. The questionnaire is composed of 8 subscales adapted from a Tool to Measure Parenting Self-efficacy - TOPSE (unpublished data). The questionnaire covers the dimensions of positive emotion, play, empathy, guiding, rules, pressures, acceptance and experience.

Ratings of children's wellbeing are measured by the parent report of KIDSCREEN-52: a questionnaire with 52 items rated on a 5-point Likert scale to measure child's mental and physical well-being, moods, relations with parents and peers, and social functioning. Assesses frequency of behaviour/feelings (never-seldom-sometimes-often-always) and intensity of attitudes (not at all-slightly-moderately-very-extremely).

Secondary outcome measures
Current secondary outcome measures as of 08/04/2013:
Program fidelity by group leaders is measured by observations of recorded program sessions. The group leaders are rated according to two dimensions. One regarding competence in terms of framework, speaking with own terms, well prepared, presenting the program in a positive manner, activating parents, strengthening parents and interaction between the two group leaders. The second dimensions cover the content of the program including presentation of the theme, presentation of goals, dimensions of parenting, discussion of the theme, and testing at home. Parent's commitment of the method is measured through questionnaires two weeks after each group meeting by questions about the use of program components ('yes/no'), and how did it work ('Positive/Both positive and negative/Negative').

Retaining of family rules as well as positive and negative parenting practices is assessed by Parenting Practices Interview (PPI). In this study the two subscales parental praise and harsh parenting were used and covered by 26 items, rated on a 7-point Likert scale (from 'never' to 'always', and from 'not likely at all' to 'extremely likely', depending on the wording of the question).

The General Health Questionnaire-GHQ12 is included to measure the parents' mental health, scored on 4-point Likert scale (Positive items - 'better/more than usual', 'same as usual', 'less than usual' and 'much less than usual', Negative items - 'not at all', 'no more than usual', 'rather more than usual' and 'much more than usual'). The 12 items will be divided into a positive scale measuring mental health/well-being and a negative scale measuring mental distress.

The brief version of the Dyadic Adjustment Scale (DAS), covered by the subscale Dyadic Satisfaction is used to measure relational satisfaction/dissatisfaction between parents. Four items on a 7-point Likert scale, ranging from 'never' to 'always', and 'extremely unhappy' to 'extremely happy', (dependent on the wording of the question) is used.

Emotion Regulation Questionnaire (ERQ), evaluates the parents' emotion regulation strategies. This is a 10-item self-report questionnaire rated on a 7-point Likert scale (from 1=strongly disagree; 4=Neutral; to 7=strongly agree). Individuals are asked to rate the extent to which they typically try to think or behave differently in situations in order to regulate their own emotions.

In the health economic evaluation, the health variable which will be explored to evaluate cost-effectiveness is health-related quality of life (HRQOL) in children measured by a parent proxy VAS-scale. Additionally, the monetary calculations will use data obtained from contact persons in municipalities/town districts, county council records and national registers.

Previous secondary outcome measures until 08/04/2013:
Program fidelity by group leaders is measured by observations of recorded program sessions. The group leaders are rated according to two dimensions. One regarding competence in terms of framework, speaking with own terms, well prepared, presenting the program in a positive manner, activating parents, strengthening parents and interaction between the two group leaders. The second dimensions cover the content of the program including presentation of the theme, presentation of goals, dimensions of parenting, discussion of the theme, and testing at home. Parent's commitment of the method is measured through questionnaires two weeks after each group meeting by questions about the use of program components ('yes/no'), and how did it work ('Positive/Both positive and negative/Negative').

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Parental emotional regulation is covered by the Affect Regulation Checklist (ARC), rated with12 items on a 7-point Likert scale ranging from 0=do not agree, to 7=completely agree. The ARC includes the two dimensions maladaptive and adaptive strategies.

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Overall study start date
09/02/2012

Overall study end date
20/06/2014

Eligibility

Participant inclusion criteria
Family can participate in the trial when the applicant is:
1. A parent or other caregiver of a child in the age of 3-12 years
2. Living in one of the participating municipalities in the County of Stockholm or in one of the city districts in the City of Stockholm

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
600 (300 in intervention group, and 300 in wait-list control group)

Participant exclusion criteria
Family cannot participate in the trial if:
1. The child is having a severe problematic or psychiatric disorder that demands other types of intervention, for example severe depression or a psychiatric diagnosis
2. Parent is in need of intervention or treatment, for example regarding domestic violence, or substance abuse or addiction

Recruitment start date
09/02/2012

Recruitment end date
20/06/2014

Locations

Countries of recruitment
Sweden

Study participating centre
Karolinska Institutet
Stockholm
Sweden
SE 104 62

Sponsor information

Organisation
Swedish National Institute of Public Health (Sweden)

Sponsor details
Forskarens väg 3
Östersund
Sweden
831 40

Sponsor type
Government

Website
https://www.fhi.se

ROR
https://ror.org/05x4m5564

Funder(s)

Funder type
Government

Funder Name
Swedish National Institute of Public Health (Sweden) ref: HFÅ 2010/90

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	29/07/2013		Yes	No
Results article	results	18/10/2014		Yes	No
Results article	6-month follow-up	15/05/2024	21/05/2024	Yes	No