

Parenting matters: helping parents with young children

Submission date	Recruitment status	<input type="checkbox"/> Prospectively registered
09/08/2005	No longer recruiting	<input type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
09/08/2005	Completed	<input checked="" type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
09/07/2013	Mental and Behavioural Disorders	

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00133055

Protocol serial number

MCT-67816

Study information

Scientific Title

Study objectives

We hypothesise that parents receiving treatment booklets addressing sleep and bedtime behaviours (Trial 1) or discipline problems (Trial 2) and telephone support, along with usual care by their family physician, will demonstrate greater reductions in sleep or discipline problems, improved parenting practices, and greater reductions in child behaviour problems in general following the intervention compared to parents receiving usual medical care.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The University of Western Ontario Research Ethics Board for Health Sciences Research Involving Human Subjects (HSREB), 08/11/2004

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Discipline and Sleep Problems

Interventions

Intervention group in each trial (trial 1 - [sleep], trial 2 [discipline] and trial 3 [both sleep and discipline]) will receive by mail a problem-specific self-help treatment booklet. Trial 3 participants will receive one of the two treatment booklets. Furthermore all of them will receive telephone support (three phone calls in total over six week treatment period) in addition to usual care by a family physician.

Control group: Usual care by a family physician.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

There are separate primary outcomes measured for each trial:

Sleep and bedtime problems trial (Trial 1): Parent report on the Children's Sleep Habits Questionnaire

Discipline problems trial (Trial 2): Parent rated total problem score on the Eyberg Child Behavior Inventory

Sleep and Discipline problems trial (Trial 3): Parent report on the Children's Sleep Habits Questionnaire (Group 1 Sleep treatment) and Parent rated total problem score on the Eyberg Child Behavior Inventory (Group 2 Discipline treatment)

Key secondary outcome(s)

1. Parenting practices - Total score on the Parenting Scale
2. General child behavior problems - Total problem score on the Child Behavior Checklist
3. Daily recall ratings of sleep and discipline problems (four reports in total)
4. Parent report on the Richman sleep questionnaire (only for trial 1 [sleep and bedtime problems] and for trial 3 participants if in sleep treatment condition)

Completion date

31/05/2007

Eligibility

Key inclusion criteria

Parents of children aged two to five years of either sex with concerns about their child's sleep (trial 1), discipline (trial 2), or sleep and discipline (trial 3):

1. Parent (primary caregiver) of 2 - 5 year old child
2. Attending a medical appointment at a family medical practice
3. Phone in home
4. Parent concerned about child's sleep and/or discipline
5. Parent interested in participating in a treatment study

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Parent non-English speaking
2. Child with significant physical (e.g. cerebral palsy) or developmental (e.g. Down syndrome) disability
3. Parents only sleep concern is in regards to a physiological sleep disorder (e.g. sleep apnea, snoring) or bedwetting

Date of first enrolment

01/01/2005

Date of final enrolment

31/05/2007

Locations

Countries of recruitment

Canada

Study participating centre

Social Sciences Centre

London, Ontario

Canada

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Sponsor information

Organisation

University of Western Ontario (Canada)

ROR

<https://ror.org/02grkyz14>

Funder(s)

Funder type

Research organisation

Funder Name

Canadian Institutes of Health Research (CIHR) (Canada) - <http://www.cihr-irsc.gc.ca> (ref: MCT-67816)

Funder Name

The Provincial (Ontario) Centre of Excellence for Child and Youth Mental Health at CHEO (Canada)

Results and Publications

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?
Results article	results	01/02/2013		Yes	No