

Parenting matters: helping parents with young children

Submission date 09/08/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 09/08/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 09/07/2013	Condition category 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
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Graham James Reid

Contact details
Social Sciences Centre
1151 Richmond Street
SSC 7310
University of Western Ontario
London, Ontario
Canada
N6A 5C2
+1 519 661 2111 (84677)
greid@uwo.ca

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00133055

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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 measure

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)

Secondary outcome measures

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)

Overall study start date

01/01/2005

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

Age group

Adult

Sex

Both

Target number of participants

480 (Added 09/08/2011: 548 actually recruited)

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

N6A 5C2

Sponsor information

Organisation

University of Western Ontario (Canada)

Sponsor details

1151 Richmond Street North

London, Ontario

Canada

N6A 3K7

Sponsor type

University/education

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

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?
Results article	results	01/02/2013		Yes	No