ISRCTN81511074 https://doi.org/10.1186/ISRCTN81511074

Parenting matters: helping parents with young children

Submission date	Recruitment status
09/08/2005	No longer recruiting
Registration date	**Overall study status**
09/08/2005	Completed
Last Edited	**Condition category**
09/07/2013	Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

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

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 childs 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 childs 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