Enhancing transparency and reducing bias through data pooling: Individual Participant Data (IPD) meta-analysis for investigating equity effects of parenting interventions

Frances Gardner
Professor of Child & Family Psychology
Centre for Evidence-Based Intervention
Dept of Social Policy & Intervention, University of Oxford

Pooled Data Analysis
N = 1799

Evidence Live, 22 June 2016. With thanks to UK NIHR-Public Health Research
Disclaimer: This is a summary of independent research funded by the National Institute for Health Research (NIHR)’s Public Health Research Programme (Grant Ref Number 12-3070-04). The views expressed are those of the authors and not necessarily those of the NHS, NIHR or Department of Health.
Acknowledgements

Project team:
Frances Gardner (PI)
Patty Leijten, Jo Mann
Oxford University, Dept Social Policy & Intervention

Stephen Scott, Child Psychiatry;
Sabine Landau, Victoria Harris,
Biostatistics - IOPPN, Kings College London

Judy Hutchings - Bangor
Jennifer Beecham, Eva Bonin – Economics, LSE

Collaborators
Bram Orobio de Castro, Utrecht
Sinead McGilloway, NUI, Ireland
Filomena Gaspar, Coimbra Portugal
Ulf Axberg, Gothenburg, Sweden
Willy-Tore Mørch, Tromso, Norway
Vashti Berry, Plymouth, UK

Advisors
George Howe, GWU
Anna Goodman, London School of Hygiene & Tropical Medicine

Thanks for funds & inspiration:
NIHR Public Health Research- 12-3070-04
Overview

• Parenting interventions for reducing child disruptive behavior
• Moderators of intervention effects:
  --- examining disparity/ equity questions
  --- limitations of usual studies - design & transparency
• How pooling **individual participant-level data** (IPD) can overcome many of these limitations
• Our study: Pooling individual-level data from near complete set of randomised trials in Europe of one parenting intervention to investigate moderators and wider benefits
Parenting Interventions

• Based on attachment and cognitive-behavioural theory
• Aim to enhance positive parenting, reduce harsh parenting
  - and through this mechanism, to reduce child disruptive behavior
• Many RCTs & SRs, much known about the main effects of these interventions
  – on child behaviour, parenting skill & confidence, parent mental health
• In society, these child outcomes are highly patterned by SES.
• But much less clear if intervention benefits are patterned by SES
Moderators and equity effects

Ask: for whom does it work: understanding intervention theory, practice, policy
Moderator analyses examine interaction effects;
Identify subgroups where intervention is suitable or does no good - improve targeting, alter or enhance intervention methods or delivery

As interventions go to scale – ask wider ‘equity’ questions about population effects of interventions on social disparities
• If interventions have differential effects, could they serve to further increase social disparities in child outcomes? - Does an ‘Inverse care’ effect operate for most disadvantaged families, whereby we help the most needy least? Access vs. effects..
• Or, will these interventions narrow the gaps?
Do more disadvantaged (i.e., low SES) and distressed (i.e., high problem severity) families show less or more improvement?

Two large reviews of parenting intervention predictor effects (567, 451 cites) (Lundahl, 2006; Reyno & McGrath, 2006)
• Tested e.g., poverty, lone parent, parental depression
• “more disadvantaged and distressed families benefit less”

Recent large trials give a different picture
“no moderator effects” or “more disadvantaged and distressed families can benefit more” (Gardner et al., 2009, 2010; Beauchaine et al., 2005).
Thus unclear what potential effects on social disparities
Individual trials
• Well powered to test main effects
• Not powered to test moderation effects (Brown, 2012)
• Criticised for ‘cherry picking’ outcomes & analyses, posthoc.
• Need pre-registration, transparent reporting to overcome this problem

Meta-analyses
• Even more power and precision for main effects BUT...
• Moderation only by trial level characteristics, eg by average level (per trial) of family characteristics
• Means all variability within trials in participant characteristics lost
• Power for moderator effects low, N only as large as the number of trials
• Trial level moderators often confounded (Lipsey, 2003)
To overcome these drawbacks, what is needed?
Pooling or Individual Participant Data meta-analysis, IPD (aka: IDA)

Benefits

• Uses all within-trial individual variability (e.g., in ethnicity, SES)
• Enhanced power to detect moderator effects; wider benefits and harms, rarer outcomes & subgroups, cost benefit
• Greater generalisability across families, service contexts, regions
• Consistent and transparent analytic strategies
• Fits with current climate pushing for greater transparency, replicability, data sharing; reduce reporting bias (eg BMJ ALLTrials campaign)
• In psychosocial field, much needed- transparency less well developed, but improving (eg new CONSORT ‘SPI’; Grant 2013; Cybulski 2016)

Challenges

• Ethical issues re consent, full anonymity
• Accessing, then interpreting data
• Harmonising varied data across trials - validity & resources
Incredible Years Pooling Study

Who benefits from parenting interventions?

Combining data from near total sample of randomized trials of the Incredible Years parenting intervention in Europe

Integrative Data Analysis

$N = 1799$
Incredible Years: What and Why?

Developed in USA, 12-14 sessions, Groups of parents of 3-8 yr olds with disruptive behaviour;

Strong evidence base—many independent RCTs in Europe;

UK policy: NICE, IAPTS-widely disseminated in children’s health & family services
Primary project goal

To examine if IY parenting intervention is less or more effective for reducing disruptive child behaviour in the most disadvantaged and most distressed families.

Social equity / disparity questions drive much of UK public health research agenda – i.e. are policies / intervention taken to scale likely to have the effect of widening or narrowing social disparities? (Tugwell et al 2006).

For main effects, do we get the same answers as we did from regular systematic reviews?

Funder- UK Public Health Research, put out request for pooled data to investigate equity effects of interventions.
Research Questions

Is there a differential effect of the IY parenting intervention on reduced disruptive child behaviour:

• by family socioeconomic status?

• by ethnic minority status?

• by child and family problem severity?

• by child characteristics - age, gender
Methods

• Sought data for complete sample of RCTs of IY parenting in Europe-searching found 15 eligible trials
• Data from 14 trials available, all PIs agreed to share data
• **Individual** and **item** level data received, cleaned and, harmonised;
• Collaborative structure (meeting every 6 months)
• Research questions limited by what available; and by whether variables operate at trial vs individual level

Resources:
- Cochrane IPD; PRISMA-IPD Statement (Preferred Reporting Items for Systematic Review & Meta-Analyses of individual participant data)
- Hendricks Brown- NIMH collaborative grp on adolescent depression
<table>
<thead>
<tr>
<th>Trial</th>
<th>Country</th>
<th>Treatment vs. Selective Prevention</th>
<th>Description of the 14 trials</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Norway</td>
<td>Indicated /Treatment</td>
<td>Psychiatric clinics</td>
</tr>
<tr>
<td>2</td>
<td>Sweden</td>
<td>Indicated /Treatment</td>
<td>Psychiatric clinics</td>
</tr>
<tr>
<td>3</td>
<td>Portugal</td>
<td>Indicated /Treatment</td>
<td>University clinic</td>
</tr>
<tr>
<td>4</td>
<td>Ireland</td>
<td>Indicated /Treatment</td>
<td>Mixed child community services</td>
</tr>
<tr>
<td>5</td>
<td>Netherlands</td>
<td>Selective prevention</td>
<td>Mothers in prison (or just released)</td>
</tr>
<tr>
<td>6</td>
<td>Netherlands</td>
<td>Selective prev, mixed</td>
<td>Immigrant families, low SES families</td>
</tr>
<tr>
<td>7</td>
<td>Wales</td>
<td>Indicated /Treatment</td>
<td>Sure Start, mixed services, low SES areas</td>
</tr>
<tr>
<td>8</td>
<td>Wales</td>
<td>Selective prevention</td>
<td>Flying Start, very low SES areas, toddlers</td>
</tr>
<tr>
<td>9</td>
<td>England</td>
<td>Indicated /Treatment</td>
<td>Birmingham, Mixed community services</td>
</tr>
<tr>
<td>10</td>
<td>England</td>
<td>Indicated /Treatment</td>
<td>London primary schools SPOKES</td>
</tr>
<tr>
<td>11</td>
<td>England</td>
<td>Selective prevention</td>
<td>London primary schools PALS</td>
</tr>
<tr>
<td>12</td>
<td>England</td>
<td>Indicated /Treatment</td>
<td>Primary schools HCA</td>
</tr>
<tr>
<td>13</td>
<td>England</td>
<td>Indicated /Treatment</td>
<td>Oxfordshire, referred cases, NGO sector</td>
</tr>
<tr>
<td>14</td>
<td>England</td>
<td>Indicated /Treatment</td>
<td>London, NHS psychiatric clinics</td>
</tr>
</tbody>
</table>
### Pooled sample (N=1799)

<table>
<thead>
<tr>
<th>Feature</th>
<th>Mean (SD) / Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Child age in years (range 2-10)</td>
<td>5.1 (1.65)</td>
</tr>
<tr>
<td>Child gender (% boys)</td>
<td>63%</td>
</tr>
<tr>
<td>Low income</td>
<td>55%</td>
</tr>
<tr>
<td>Lone parent</td>
<td>34%</td>
</tr>
<tr>
<td>No employed parent in household</td>
<td>27%</td>
</tr>
<tr>
<td>Parent: Lower secondary education and below</td>
<td>46%</td>
</tr>
<tr>
<td>Ethnic minority background</td>
<td>28%</td>
</tr>
</tbody>
</table>
Data availability & harmonisation

- Reasonably full data on child disruptive behaviour, parent depression, & main demographic variables
- Huge job to harmonise across trials, despite many trials using similar measures. Had to use different methods for different variables
- Contextual information- lots, but N= 14 very limiting.
- **Harmonisation: used norm deviation scores:** for child disruptive behaviour (outcome & moderator; 2 measures) and parental depression (moderator; 5 measures)
- Socioeconomic status: **dichotomised risk factors** (low income, unemployment, lone parent)
Analysis strategy

• Primary outcome: Child disruptive behaviour at post-test.
• 13 trials had data on this, N= 1696 for moderator analyses.
• One stage analysis of pooled data only, Intent-to-treat
• Multilevel modelling to analyse effects of moderators on children, nested in parenting groups, nested in trials
• Random effects models to reflect hierarchical data structure
• Fixed effects to model moderator effects of interest.
• Multiple imputation of missing data (MICE)- using all available variables, separately by arm, by trial.
• Controlled for key baseline variables (child behaviour, age, gender, selective prevention vs indicated/ treatment trial)
• Explored potential confounders of sig moderator effects
Effects of IY parenting, per trial

Intervention effect size on child disruptive behavior Cohen’s $d$ (Eyberg Child Behavior Inventory)
Children in a low income family- will they benefit more or less than those in higher income families?

What would you predict?

(‘Benefit’ expressed in terms of change in the primary outcome, parent reported child disruptive behaviour (ECBI) Moderator variable is binary)
No evidence to suggest IY effect on child disruptive behaviour varies by low vs average-high income ($p=0.87$).

No moderation effect.
Child in family where **no parent** is employed -
Will they benefit more or less?
No parent employed (SES)

- No evidence to suggest that IY effect varies by parent unemployment vs employed ($p=0.42$).

- No moderation effect.
Child in lone parent family-
Will they benefit more or less?
- No evidence to suggest that IY effect varies by lone parent/ vs. partnered ($p=0.99$).

- No moderation effect.
Child in ethnic minority family-
Will they benefit more or less?
No evidence to suggest IY effect varies by ethnic minority vs. not ($p=0.48$).

Mostly UK, Holland, 7 trials.
Child whose parent has a higher level of depression (continuous score)
Will they benefit more or less?

- high burden of depression in families experiencing child mental health and behavioural problems
Parental depression

Evidence of effect moderation (p=0.01)
- Children of parents with higher depression benefit more.

No evidence of a non-linear relationship (p=0.22)
Child with higher or clinical levels of disruptive behaviour at the start (continuous score)-Will they benefit more or less?
Baseline child disruptive behaviour problems (ECBI)

- Evidence to suggest effect varies with baseline level of behaviour problems ($p=0.015$).
- Children with higher scores at baseline benefit more.
- No evidence for non-linear effect ($p=0.79$).
Younger vs. older children, range 2-10
Will they benefit more or less?
(age as continuous variable)

Think of policy thrust..
First 1000 days;
Heckman ... etc

Source: Heckman (2008)
No evidence to suggest that IY effect varies with child age \((p=0.95)\).

No moderation effect

No evidence for non-linear effect \((p=0.698)\)
Main effects- wider benefits of parenting intervention

<table>
<thead>
<tr>
<th>Effects of parenting on outcome:</th>
<th>Source: Pooled data main effects</th>
<th>Source: Cochrane reviews (eg Furlong 2012)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disruptive behaviour</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>ADHD</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Emotional problems</td>
<td>NO</td>
<td>YES</td>
</tr>
<tr>
<td><strong>Parent depression</strong></td>
<td>NO</td>
<td>YES (2 REVIEWS)</td>
</tr>
<tr>
<td>Parenting skill</td>
<td>YES</td>
<td>YES</td>
</tr>
</tbody>
</table>

Comparing our IPD main effects with findings of systematic reviews of similar interventions..

Reporting bias?
IPD improving transparency?
+ caveats..
Conclusions

In our pooled data analyses, few moderator were effects found: Children appear just as likely to benefit from this parenting intervention, in terms of change in disruptive behaviour:

- If they come from a low income, jobless or lone parent family, or from an ethnic minority.

- But - if family has high levels of distress at outset, i.e. more severe child disruptive behaviour, or parent higher levels of depression, they are more likely to benefit.

- No age effects - interesting, first well powered study on this; does not fit with thrust of neuroscience /early intervention work.

- Findings re. main effects on secondary outcomes don’t entirely concur with data from systematic reviews.
Implications & puzzles -

• First study with adequate power to confirm ‘no moderator’ findings, in terms of SES and ethnicity.
• Dissemination of programme unlikely to increase social disparities in these outcomes, e.g., by SES, ethnicity.
• Hard to answer these equity questions without pooled data. Conventional meta-analysis not really up to it
• Why is IY parenting programme effective across diverse groups? Why no age effects?
• Importance of pooled data to yield more powerful, transparent, and generalizable findings. Data sharing...making full use of data we have..
THANK YOU

Professor Frances Gardner
Centre for Evidence-Based Intervention,
Dept of Social Policy & Intervention, University of Oxford
frances.gardner@spi.ox.ac.uk


Extra/explanatory slides
Harmonising socioeconomic status

**Low income**: Family has—or is very likely to have—low income as defined by:
[1] receiving financial benefits (10 trials), [2], having below median income (1 trial),
[3] scoring below low SES threshold on the Hollingshead Index (1 trial), or
[4] living in social housing or with family instead of renting/owning house (2 trials).

**Educational level**: Highest educational level of primary parent, according to
simplified version of ISCED-11, *UNESCO Institute for Statistics (2011).*
1 = Primary education or lower secondary with no qualifications
2 = Lower secondary education
3 = Upper secondary education
4 = Post-secondary (including short cycle tertiary) education
5 = Bachelor’s / Master’s / Doctoral degree

**Teen parent**: Primary parent was younger than 20 years at birth of target child.

**Lone parent**: Primary parent does not live with partner/spouse.

**Parental unemployment**: No employed parent in household.
Norm deviation scores

For child behaviour problems and parental depression we used normative population means and standard deviations to help with harmonisation.

**Step 1:** Selected primary outcome measure (e.g., most frequently used measure, reliable norm scores)

**Step 2:** For studies that did not include the primary outcome measure, selected the most optimal other measure (focusing on the same construct, available norm scores)

**Step 3:** Converted scores from these ‘secondary measures’ into norm deviation scores.

E.g., CBCL population $M=100$, $SD=10$, a child with score 120 gets a norm deviation score of 2 (i.e., 2 SDs above the norm)

**Step 4:** Converted norm scores to original scale of the primary outcome measure.

E.g., ECBI population $M=120$, $SD=25$, the same child gets an ‘ECBI score’ of 170 ($120+2\times25$).

**Where possible we used**: Gender and age specific norm scores
Norm deviation scores

Advantages
- All data from the measures are used
- Original response scale of primary outcome measure maintained
- Can be used regardless of differences in response scales

Assumptions
- Both instruments measure the same construct
- Both instruments have the same measurement error
- Population norm scores come from similar populations

Disadvantages
- Not all widespread scales have norm scores which are of good quality (and when are they good enough?)
Norm deviation scores

For example: **Child conduct problems**

Eyberg Child Behavior Inventory (ECBI) was used in 11 of 13 trials that had parent reported child conduct problems. Parental Account of Children’s Symptoms (PACS) was used in the other 2 trials.

PACS scores were converted into norm deviation scores (i.e., how many standard deviations does this child score above or below the population mean?).

These norm deviation scores were then converted into ECBI scores (i.e., which ECBI scores is reflected by this number of standard deviations above or below the population mean?)
Socioeconomic Status

**Low income:** Family has—or is very likely to have—low income. Based on receiving financial benefits (10 trials), benefits and low income (1 trial), social housing (2 trials), Hollingshead Index (1 trial).

**Educational level:** Highest educational level of primary parent
1 = Primary education or lower secondary with no qualifications
2 = Lower secondary education
3 = Upper secondary education
4 = Post-secondary (including short cycle tertiary) education
5 = Bachelor’s / Master’s / Doctoral degree

**Teen parent:** Primary parent was younger than 20 years at birth of target child.

**Lone parent:** Primary parent does not live with partner/spouse.

**Parental unemployment:** No employed parent in household.
Item level matching

Advantages

- High face validity
- Original response scale (of most scores) maintained

Assumptions

- Items measure the same construct
- Items have the same measurement error
- All items within a construct have the same weight

Disadvantages

- Items are hardly ever identical in the construct they measure
- Items hardly ever have same time period (‘last week’, ‘last month’)
- Items hardly ever have same response scale (‘never to always’, ‘number of times per day’)

45
Item level matching

Used for measures of (partly) similar constructs - measures for parenting practices

Step 1: Selected similar items across measures
   e.g., items that reflect corporal punishment (e.g., hitting, spanking etc.)
Step 2: Averaged item scores per measure
Step 3: Decided on reponse scale (e.g., scale most frequently used)
Step 4: Converted all scores into decided response scale

Checked:
- Similarities in questions (e.g., period/situations) and
- Scales (e.g., never to always, number of times per day)
- Compare distribution and means across measures?
Item level matching eg – self reported corporal punishment

**Item from the PS (1 item: 18) (7-point scale) (5 trials)**
- I spank, grab, slap, or hit my child “most of the time” (vs “never or rarely”)

**Items from the PPI (6 items: 1h, 1i, 2h, 2i, 3h, 3i) (7-point scale) (3 trials)**
How often do you do each of the following things when your child misbehaves?
- Give your child a spanking
- Slap or hit your child (but not spanking)
If your child hit another child, how likely is it that you would discipline your child in the following ways?
- Give your child a spanking
- Slap or hit your child (but not spanking)
If your child refused to do what you wanted him/her to do, how likely is it that you would use each of the following discipline techniques?
- Give your child a spanking
- Slap or hit your child (but not spanking)

**Items from the APQ (3 items: 31, 33, 36) (5-point scale) (1 trial)**
- You spank your child with your hand when he/she has done something wrong
- You slap your child when he/she has done something wrong
- You hit your child with a belt, switch, or other object when he/she has done something wrong

**Items from parenting interview (1 item) (5-point scale) (4 trials)**
- Thinking about last week, how many times did you give your child a tap or smack if they misbehaved?