

REVIEW

Pragmatic randomised controlled trials in parenting research: the issue of intention to treat

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J Epidemiol Community Health 2006;60:858–864. doi: 10.1136/jech.2005.044214

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Accepted for publication
25 February 2006

Study objective: To evaluate trials of parenting programmes, regarding their use of intention to treat (ITT).
Design: Individual trials included in two relevant Cochrane systematic reviews were scrutinised by two independent reviewers. Data on country of origin, target audience, trial type, treatment violations, use of ITT, and the management of missing data were extracted.

Main results: Thirty trial reports were reviewed. Three reported the use of an ITT approach to data analysis. Nineteen reported losing subjects to follow up although the implications of this were rarely considered. Insufficient detail in reports meant it was difficult to identify study drop outs, the nature of treatment violations, and those failing to provide outcome assessments. In two trials, study drop outs were considered as additional control groups, violating the basic principle of ITT.

Conclusions: It is recommended that future trial reports adhere to CONSORT guidelines. In particular ITT should be used for the main analyses, with strategies for managing treatment violations and handling missing data being reported a priori. Those conducting trials need to acknowledge the social nature of these programmes can sometimes result in erratic parent attendance and participation, which would only increase the chances of missing data. The use of approaches that can limit the proportion of missing data is therefore recommended.

Early investment in the lives of children is recognised by the World Health Organisation, the United Nations Population Fund, The World Bank, and Family Health International as a global policy imperative to reduce rates of premature death in the poorest parts of the world. Moreover, interventions that are able to combine support for both the physical and psychological needs of children, by providing guidance aimed at strengthening parent-child relations, will have additional benefits for the survival of those within disadvantaged communities.¹ One means of doing this has been through the provision of programmes addressing parenting practices.

The presence of parenting as an area of interest in UK government policy corresponds to the simultaneous attention on crime and antisocial behaviour.² A connection between parenting practices, early life experiences, and later behaviour has been repeatedly referred to and has led to the development in the UK of new modes of service delivery such as Sure Start and, more latterly, Children's Centres.³ These programmes, like their forerunner the United States Head Start programme,⁴ have been developed for young families living within socially disadvantaged communities. The Sure Start programme has radically influenced the way in which community health services for children are now organised within the UK. Moreover the message from UK national policy is that parents need supporting⁵ given that they are the most important influence in the lives of growing children³: a political will that is perhaps fuelled by the simultaneous desire to reduce crime and improve training and employment chances, as the basis for a stable national economy?⁶ Regardless of motive, this political climate has opened the way for the development of numerous parenting support programmes within the UK.⁷ This has supported a growth in what might be described as the "parenting support industry" creating parenting programmes as commercial products. As a consequence, the National Institute for Health and Clinical Effectiveness (NICE) for UK health and social care services has recently published its own appraisal of the effectiveness

of these programmes⁸ and in the same month the UK Home Office Respect Task Force has launched plans to expand parenting provision nationally.⁹ This reinforces the need for parenting interventions to be supported by credible evidence¹⁰ and thus subject to criteria endorsed by the evidence based healthcare movement.^{11 12}

Traditionally, the strongest evidence of effectiveness is shown using rigorous evaluation methods, specifically the randomised controlled trial (RCT). However, it is the quality of the application of methods rather than the method itself that should be the primary concern.¹³ The purpose of this paper is to explore the application and the quality in the reporting of RCTs in parenting. To date, the RCT has been one of the main methods used in the evaluation of parenting interventions, possibly to address the scepticism that exists about the justification for using public money to fund parenting support. Critics of the use of RCTs in evaluating socially complex interventions highlight issues regarding homogeneity of the intervention received.^{14–16} In parenting trials, factors affecting homogeneity may include the interaction between parents and practitioners and parents dipping in and out of programmes without necessarily withdrawing. This reinforces the need for good research design, careful and thoughtful analysis and reporting. The Medical Research Council framework for the evaluation of complex interventions¹⁷ recognises these issues to some degree. It notes that traditional principles of evaluation may be applied to a complex intervention, and appreciates the importance of early theoretical work in identifying its active ingredients and their interrelationships. However, it fails to provide clear guidance on the analytical issues relating to intention to treat (ITT).

PRAGMATIC RANDOMISED CONTROLLED TRIALS

There are essentially two types of RCTs: explanatory (sometimes now termed fastidious) and pragmatic. A trial that is explanatory will provide evidence of efficacy of the experimental intervention in ideal conditions, preferably when

compared with a placebo. A pragmatic trial however should study clinical effectiveness in relation to current best practice.¹⁸ However, pragmatic and explanatory attitudes are likely to coexist in some trials¹⁹ (for example, the use of both sham acupuncture and “no treatment” control groups in acupuncture trials).

A key feature of pragmatism in RCTs is the management of missing data, or data obtained from participants who did not progress through a trial as planned (often termed treatment or protocol violators). Although allocating participants in a random manner is vital to assure an unbiased estimate of clinical effectiveness, there is the potential for participants not to receive the planned or minimum level of intervention as detailed in the trial protocol. The CONSORT (consolidated standards of reporting trials) statement has in recent years set a benchmark for the quality of clinical trial reporting. The first CONSORT statement was published in the *Journal of the American Medical Association* in 1996²⁰ with a revision published in 2001.²¹ This revision proposes 22 items requiring consideration in a trial report, and recommends the use of a flowchart to show patterns of subject recruitment, withdrawal, and completion. Critically, the CONSORT guidelines state that reports of RCTs should state how an ITT was implemented in the analysis of data. Despite CONSORT, reviews would suggest that this is rarely followed.^{22 23}

The first reference to ITT within health literature is attributed to Austin Bradford Hill²⁴ (page 258) and may have appeared in editions of his book dating back to the 1950s.²⁵ He stated “unless the losses are very few and therefore unimportant, we may inevitably have to keep such patients in the comparison and thus measure the intention to treat in a given way rather than the actual treatment. The question of the introduction of bias through exclusions for any reason (including lost sight of) must, therefore, always be carefully studied, not only at the end of a trial but throughout its progress. This continuous care is essential in order that we may immediately consider the nature of the exclusions and whether they must be retained for enquiry for follow-up, measurement etc. It will be too late to decide that at the end of the trial”.

While there is no standard definition of ITT, the American Statistical Association (ASA) gave what is probably the most widely accepted version: “an intention to treat analysis is one which includes all randomised patients in the groups to which they were randomly assigned, regardless of the compliance with the entry criteria, regardless of the treatment they actually received, and regardless of subsequent withdrawal from treatment or deviation from the protocol”.²⁶ It is claimed that using an ITT approach in the analysis reduces the possibility of overestimating any clinical effectiveness^{23 27} and is therefore most suitable for pragmatic RCTs.

Additionally, on initial consideration of the ASA definition, it might seem that using an ITT approach to analysis is a straightforward process, with complete data being available for all participants whether they withdraw, comply or not. In practice this is rarely the case. There is the potential for any missing data to introduce bias.^{28 29} Standard methods for analysing data rely on the assumption that any data missing are so for reasons unrelated to their potential values. However, this necessary assumption for the validity of analyses cannot be formally tested without the actual data. While some reasons for missing data (for example, incorrectly enrolling ineligible participants in the trial) are less likely than others (for example, withdrawal because of side effects or lack of efficacy) to cause substantive bias in estimating effectiveness, it will still be difficult to provide a convincing argument that the missing data can be ignored. For example, the failure to complete outcome assessment in a

study of a parenting programme, for whatever reason, would need to be unrelated to the programme’s outcomes for those families to allow the data analyst to validly ignore any missing data.

Strategies have been proposed for the management of missing data, many of which entail considering one or more plausible potential reasons for data being missing. Based on these alternative reasons, values should be imputed (filled in) and the sensitivity of the conclusions assessed. While last observation carried forward (LOCF) is the most commonly applied imputation method in trials with repeated outcome assessment, many authors have been critical of its widespread application.³⁰⁻³³ It leads to bias in the estimation of the of clinical effectiveness, but the magnitude and direction of the bias can only be surmised. Moreover, substituting a fixed value, such as the group mean, will artificially reduce the variability and increase the sample size, thus reducing the standard error. This will increase the type I error rate above that stated, making it more probable that clinical effectiveness is concluded incorrectly. The recommendation now made in the literature (for example, Verbeke *et al*³⁰) is that LOCF should be used with caution.

EXPLORATORY REVIEW

This paper will report an exploratory review of the current position regarding ITT in parenting research. A representative pool of RCTs in parenting was sought so that data collection and analysis techniques could be scrutinised. A decision was taken to use systematic reviews in parenting identified from the Cochrane database of systematic reviews as, by definition, these reviews should contain the most rigorously conducted trials in this area.³⁴ Two suitable systematic reviews were identified focusing on the effectiveness of parent-training programmes,³⁵ and the relative merits of individual compared with group parenting programmes.³⁶ Both reviews are current, and were updated in 2003 and 2001 respectively. Individual trial reports identified in the systematic reviews were obtained for analysis and data extracted independently by two reviewers (KW and CS). Extracted data related to the country of origin, target audience, type of trial, reported treatment violations, explanations regarding the reported use of ITT and claims regarding missing data. A third reviewer (CB) was used to support decision making where the appraisal of papers was complex.

RESULTS

A pool of 30 papers³⁷⁻⁶⁶ was available for review (table 1). Issues that necessitated the involvement of the third reviewer were identified in four of the papers. This was principally to clarify the issues relating to unconventional study designs.

Most of the trials were conducted in North American countries (n = 23). Most were reported in the 1990s (n = 22) with a minority in the 1970s and 1980s (n = 5). Only three papers were published since 2000. Twenty four of the papers were published in psychology oriented journals.

RANDOMISATION

None of the papers with the exception of Patterson *et al*³⁸ provided a flowchart to illustrate numbers of subjects randomised or lost during the course of the study. In total 25 of the papers reported RCTs, four of which used cluster randomisation, and four papers reported an experimental design with no random allocation of subjects. As the non-randomised studies differ in their philosophy and the overarching principle of ITT, namely to maintain a comparison of randomised groups does not apply, we shall not consider further these studies.^{37 49 56 57} One further paper⁵⁴ was difficult to classify as it reported the results of two

Table 1 Summary of papers reviewed

Author	Date	Journal type	Country	Trial type
Anastopoulos <i>et al</i> ⁶⁷	1993	Psychology	America	Not RCT
*Black and Teti ³⁸	1997	Medical	America	RCT
Blakemore <i>et al</i> ⁵⁹	1993	Psychology	Canada	RCT
Cunningham <i>et al</i> ⁴⁰	1995	Psychology	Canada	Cluster RCT
Gammon and Rose ⁴¹	1991	Social Work	America,	RCT
Greaves ⁴²	1997	Psychology	Australia	RCT
Gross <i>et al</i> ⁴³	1995	Nursing	America	RCT
Irvine <i>et al</i> ⁴⁴	1999	Psychology	America	RCT
Joyce ⁴⁵	1995	Psychology	Australia	Cluster RCT
*Koniak-Griffin <i>et al</i> ⁴⁶	1992	Medical	America	RCT
*Lagges and Gordon ⁴⁷	1999	Psychology	America	Cluster RCT
McGillicuddy <i>et al</i> ⁴⁸	2001	Psychology	America	RCT
Mullin <i>et al</i> ⁴⁹	1994	Psychology	Ireland	Not RCT
Nicholson <i>et al</i> ⁵⁰	2002	Psychology	America	RCT
Nixon and Singer ⁵¹	1993	Psychology	America	RCT
Odom ⁵²	1996	Nursing	America	RCT
Patterson <i>et al</i> ⁵³	2002	Medicine	UK	RCT
Pisterman <i>et al</i> (combined studies) ⁵⁴	1992	Psychology	Canada	Other
Pisterman <i>et al</i> (study 2) ⁵⁵	1992	Psychology	Canada	RCT
Schultz <i>et al</i> ⁵⁶	1993	Psychology	Australia	Not RCT
Scott and Stradling ⁵⁷	1987	Psychology	UK	Not RCT
Sheeber and Johnson ⁵⁸	1994	Psychology	America	RCT
Sirbu <i>et al</i> ⁵⁹	1978	Psychology	America	RCT
Spaccarelli <i>et al</i> ⁶⁰	1992	Psychology	America	RCT
Taylor <i>et al</i> ⁶¹	1998	Psychology	Canada	RCT
*Truss <i>et al</i> ⁶²	1977	Psychology	America	RCT
Van Wyk <i>et al</i> ⁶³	1983	Psychology	South Africa	RCT
Webster-Stratton <i>et al</i> ⁶⁴	1988	Psychology	America	RCT
Wolfson <i>et al</i> ⁶⁵	1992	Psychology	America	RCT
Zimmerman and Jacobsen ⁶⁶	1996	Psychology	Canada	Cluster RCT

*Papers^{38 46 47 62} were included within the Coren and Barlow³⁶ review, the remainder were included within the Barlow *et al*⁶⁵ review

separate RCTs (one of which was also separately reported).⁵⁵ For the purpose of this review, these papers are considered separately, as in the original systematic review.

Even with those papers identified as RCTs, the identification of group allocation proved to be a challenge as some papers described an unconventional study design. For example Truss *et al*⁶² had a group of 56 subjects who did not attend the experimental intervention sessions as originally randomised. These subjects were subsequently analysed as a separate control group. A second example was Gross *et al*⁴³ where again two control groups were used, as the early drop outs ($n = 7$) from the intervention group were analysed separately despite the fact they had been originally randomised into the treatment group. Additionally, and extrapolated from details of parent drop outs, at least 435 parents must have been randomised in the Cunningham *et al* paper,⁴⁰ but only 150 entered the intervention phase.

INTENTION TO TREAT

Only two papers claimed to use ITT. The first⁶¹ reported on a Canadian study and was published in 1998 in a mental health/psychology journal. The second⁵³ reported on a UK study and was published in a medical journal. In both studies, subjects were followed up according to their original allocation, but where data were missing because of failure to respond, subjects were excluded from the relevant analyses (see table 2).

In a further paper, the main principles of ITT are applied,⁴⁴ but the authors do not make an explicit claim nor use the terminology ITT. Instead they state: "because this was designed as an effectiveness trial, the analyses presented below used all of the data available after randomization, regardless of whether the parents attended any group sessions" (page 813). In effect they tried to include all subjects originally recruited to the study. This is an American study published in a psychology journal.

In seven of the RCTs (six individually randomised and one cluster randomised) it was implied or stated that no subjects

dropped out of the study and that no outcome data were missing (see table 2). In the remaining 19 randomised trials, there was some reporting of lost subjects, although the detail of this reporting was highly variable and the implications were rarely discussed (see table 2). Furthermore, the limited consistency in style of tabular presentation of data, with the absence of sample sizes, introduced additional challenges when interpreting study results. Five of the studies reporting missing data indicated that small payments had been made to participating parents,^{47 50 51 61 62} and despite this treatment violation had still occurred. Some studies^{40 44} analysed the demographic features of drop outs and participants or completed an attrition analysis.⁶⁰ In another paper³⁸ a comparison of baseline and demographics data was made between those who dropped out and those who completed the study was performed. In two trials^{43 62} the most basic principle of ITT was violated when drop outs from the intervention group were analysed as another control group.

A differentiation between treatment violators and non-responders was not always made.^{38 51} Equally, when treatment violation had been identified either as a result of programme drop out or partial non-attendance at sessions, it was not always clear whether outcome data had still been provided. It was therefore not always possible to ascertain numbers of participants who dropped out of the study, dropped out of the programme, failed to fully comply with the treatment regimen, and who did none of the above but simply failed to complete particular outcome assessments.

DISCUSSION

The case to improve the quality of community health research has been established.⁶⁷ The CONSORT guidelines provide a useful quality assurance benchmark for the reporting of RCTs in health care, and some journals (for example, *BMJ*) require that submitted papers are cross referenced to the guidelines on first submission of a paper. While the guidelines refer to a wide range of relevant issues, this paper has focused on the consideration of ITT, which reinforces the pragmatic stance

Table 2 Reporting of ITT principles

Author	ITT principles followed?	Treatment violators?	How treatment violators were managed?	Missing data? How missing data were managed?
Black and Teti ³⁸	No	Unclear	Non-attenders were indistinguishable from non-responders.	Yes Data were excluded, but drop outs were compared with the others for demographic variables and first visit data (baseline).
Blakemore <i>et al</i> ³⁹	No	No	No comment given/reported.	No
Cunningham <i>et al</i> ⁴⁰	No	Yes	Non-attenders were included in analysis where outcome data were available.	Yes Drop out from all three groups before and after randomisation. Data were excluded, but did detailed analysis of demographic characteristics of drop outs and participants by treatment group.
Gammon and Rose ⁴¹	No	No	No comment given/reported.	No
Greaves ⁴²	No	No	No comment given/reported.	No
Gross <i>et al</i> ⁴³	No	Yes	One lost in treatment through illness was excluded from inferential analysis.	Yes Early pre-treatment drop outs were analysed as separate control group.
Irvine <i>et al</i> ⁴⁴	Yes	Yes	All data were used where possible regardless of treatment attendance.	Yes The analytical method used allowed data on individual with missing data at some time points to be included, although the missing data themselves are still not accounted for.
Joyce ⁴⁵	No	No	No comment given/reported.	No
Koniak-Griffin <i>et al</i> ⁴⁶	No	No	No comment given.	No
Lagges and Gordon ⁴⁷	No	Yes	Included those missing some of the sessions where outcome data were available.	Yes Excluded all those with missing data. In addition the only two male respondents were excluded from the analysis.
McGillicuddy <i>et al</i> ⁴⁸	No	Yes	Reports overall attendance was 89%. Those missing sessions were followed up with handouts and were included where outcome data were available.	Yes Excluded all those with missing data and one additional parent from the skills training programme based outlier scores for parental anxiety.
Nicholson <i>et al</i> ⁵⁰	No	No	Those missing a session had their session rescheduled.	Yes Data excluded only when missing for relevant analyses.
Nixon and Singer ⁵¹	No	Unclear	Non-attenders were indistinguishable from non-responders.	Yes Data were excluded for drop outs
Odom ⁵²	No	Yes	Non-attenders were excluded	Yes Data were excluded for dropouts
Patterson <i>et al</i> ⁵³	Yes	Yes	Included those missing some of the sessions where outcome data were available.	Yes Data excluded only when missing for relevant analyses. However, exclusion is only due to non-completion of outcome measures and may not depend on treatment.
Pisterman <i>et al</i> ⁵⁴ (combined studies)	No	Yes	Unclear whether excluded those not attending treatment.	Yes Data were excluded for drop outs.
Pisterman <i>et al</i> ⁵⁵ (study 2)	No	Yes	Limited comment made, but did not seem to exclude those missing some of the sessions.	Yes Data were excluded for early drop outs.
Sheeber and Johnson ⁵⁸	No	Yes	Non-attender was excluded	Yes Data were excluded for drop out
Sirbu <i>et al</i> ⁵⁹	No	No	No comment given/reported.	No
Spaccarelli <i>et al</i> ⁶⁰	No	Yes	Non-attenders were excluded.	Yes Data were excluded for drop outs, but did an attrition analysis to see what factors affect likelihood of attrition.
Truss <i>et al</i> ⁶²	No	Yes	Non-attenders were partially excluded. Those only missing sessions were analysed as separate control group.	Yes Data were excluded for drop outs.
Taylor <i>et al</i> ⁶¹	Yes	Yes	Non-attenders were followed up by therapist and data collected where possible. These included in analysis.	Yes Excluded all those with missing data (no special analysis of non-attenders, for example, sensitivity analyses).
Van Wyk <i>et al</i> ⁶³	No	No	No comment given/reported.	No
Webster-Stratton <i>et al</i> ⁶⁴	No	Yes	Non-attenders were excluded when missing more than 50% of sessions.	Yes Excluded all those with missing data.
Wolfson <i>et al</i> ⁶⁵	No	No	No apparent treatment violation.	Yes Excluded all those with missing data from the relevant analyses.
Zimmerman and Jacobsen ⁶⁶	No	Yes	Non-attenders were excluded when missing more than two sessions.	Yes Excluded all those with missing data.

required in the evaluation of effectiveness. Both the ITT approach to the management of participant drop out and treatment non-concordance are important features of the pragmatic trial. In particular CONSORT suggests the use of a diagrammatic description of the flow of participants through the trial and a clear statement as to how many participants were included in each analysis.

None of the papers in our review makes reference to the CONSORT statement. Only one⁵³ attempted to present participant progress through the study using a flowchart. This may be partly because studies predated the CONSORT guidelines, although none of the papers predates the emergence of ITT. Additionally only two of the papers^{38 53}

were published in journals currently on the CONSORT list of those endorsing support.⁶⁸ It may be that health professionals are seeking to use evidence from allied disciplines (psychology and social work), which may not be applying the same criteria for maintaining scientific rigour when reporting RCTs. This results in evidence regarding parenting interventions that is difficult to evaluate and hence use effectively for healthcare decision making purposes. This might improve given recent organisational endorsement for CONSORT statements from bodies such as the American Psychological Association and the Evidence-based Behavioral Medicine Committee. Indeed there is an emerging discussion and

promotion of CONSORT standards within in the psychological literature.^{69–73}

The adoption of ITT as a strategy for clinical trials can be viewed in part as a testament to a shift towards pragmatism in research, and is strongly recommended in the CONSORT statement.²¹ While there is no single directive as to how to perform an ITT analysis, it is consistently recommended that outcome data should be analysed by the group to which subjects were randomised, regardless of the actual treatment received or its intensity.²⁸ The lack of application of and adherence to ITT is disappointing; especially in view of the numbers of studies reporting treatment violation ($n = 15$). Moreover, we found trials that overtly violated this most basic principle, forming additional control groups using those who dropped out of the study after randomisation.^{43 62}

Hollis and Campbell²³ provide more detailed recommendations for the conduct of ITT. These include the provision of an a priori statement of inclusion criteria (if any), which, if violated, would lead to the exclusion of participants from an ITT analysis. In addition they recommend minimising the period between randomisation and starting treatment to limit the potential for participants dropping out before the start of their treatment. If there is a substantial time delay before starting treatments, or there is an important task for the participants to complete between randomisation and starting treatment, including providing informed consent, then there is the potential for substantial drop out. For example, we saw that Cunningham *et al*⁴⁰ randomised families in blocks to one of three trial arms before gaining their consent, resulting in a very low percentage of those randomised to the active intervention actually starting treatment. Fergusson *et al*⁷⁴ concur with the International Conference on Harmonisation (ICH) Guidance on Statistical Principles for Clinical Trials⁷⁵ by suggesting that participants who have not taken at least one dose of the trial drug can be excluded providing there is reasonable assurance that their exclusion will not introduce bias. They also agree that ineligible participants may also be excluded as long as the assessment of eligibility is done in a fair manner and not affected by events that occur (crucially) after randomisation. Therefore, the consensus seems to be that trialists should:

- apply the highest possible standards of design to limit problems that might lead to the consideration of post-randomisation exclusions;
- exclude subjects from the primary analysis only if there is a supporting and convincing argument that such action will not lead to more than minimal bias.

Both Lachin²⁹ and Shih⁷⁶ suggest that ITT is as much about good design as analysis and the ICH Guidance on General Considerations for Clinical Trials⁷⁷ states that the protocol “should specify procedures for the follow-up of patients who stop treatment prematurely” (page 9). Montori and Guyatt⁷⁸ suggest using a protocol that ensures maximum adherence to the trial conditions (for example, use run-in period where possible and exclude any participants who do not comply

What this paper adds

This paper highlights how ITT has been poorly adopted in parenting trials and how standards of reporting vary across disciplines. This has limited the credibility of evidence behind parenting support and shows the need for future research to adhere to CONSORT guidance during the conduct and reporting of new work.

Policy implications

- Local service providers, such as Sure Start, charged with developing family support services for local communities should be aware that the current evidence that underpins national guidelines for parenting programmes is methodologically weak and poorly reported.
- Parenting education and support should continue to be recognised as an international policy priority. However, if it is to be translated into relevant action, national policies need to be informed by stronger evidence of what works in parenting support.
- Improvements to the design and delivery of future parenting programmes, will be dependent on the funding available for rigorous research. Those commissioning services should also support the need for investment in well designed and clearly reported trials of programme effectiveness.
- Journal editors have a responsibility to support improvements in clinical trial reporting by requiring researchers to show an adherence to CONSORT guidance as a prerequisite for publication.

with treatment), and make recommendations for dealing with “loss to follow up”.

In seven RCTs it was stated or implied that no outcome data were missing; this is an unlikely scenario in most pragmatic trials. Indeed, Schulz *et al*⁷⁹ found that trials that did not report any exclusions or missing data were methodologically weaker in other respects than those with some reported missing data, strongly suggesting that, in at least some cases, participants were excluded but this was not reported. Among the remaining reports of RCTs, several authors did not clarify how many participants did not provide data, with the only indication of the number of responses analysed being the reported residual degrees of freedom. While the CONSORT statement^{21 28} indicates that the number of participants included in each analysis and whether the analysis was by “intention to treat” should be clearly stated, others (for example, Hollis and Campbell,²³ Shih,⁷⁶ and Montori and Guyatt⁷⁸) go further than this. In particular Shih⁷⁶ recommends: reporting reasons for drop outs and proportions for each treatment group; conducting sensitivity analyses to encompass different scenarios of assumptions (for the pattern of missing responses), discussing consistencies or inconsistencies between them; paying attention to minimising the potential for missing data when designing the trial, including every effort to collect post-drop out data on the primary outcome variable(s); considering defining drop out as a further primary outcome variable.

Four papers^{38 40 44 60} followed Shih’s recommendations to some extent, by including some attempt to investigate the robustness of their conclusions to the missing data. In the remainder the reporting was more rudimentary showing the potential for substantial bias that could have been considerably reduced by the application of ITT. The four that did, compared the baseline characteristics of those who provided outcome data and those who did not. However, the randomisation procedure adopted by Cunningham *et al*⁴⁰ led to an undesirable level of drop out. Despite their subsequent investigations of comparability between those enrolling and not enrolling on the programme, the potential for substantial bias remained. None of the other three reported studies^{38 44 60}

found a difference in the characteristics, so did not perform any further sensitivity analyses. Cunningham *et al* did, however, obtain information on the acceptability of the programme and the characteristics of those likely to complete such a programme (at least within the setting of a pragmatic RCT). Such information is vital for those organising parenting programmes as part of broader strategies aimed at improving local child population health. In the real world of parenting programme delivery courses can last up to 8–10 weeks and are invariably dependent on the availability of key resources such as community venues and creche places. Thus the socially bound nature of programmes makes it reasonable to expect a variety of patterns of attendance and participation from parents. This makes the conduct of trials inherently difficult and the adherence to ITT all the more relevant.

It is recognised that the use of exemplar reviews necessarily limits the external validity of our findings to parenting research in general. However, many of the concerns we have identified are evident within both systematic reviews explored in this paper. It is hoped that this paper will contribute to an academic debate on the advances in trial methodology, and their implications for future trial design and reporting. In particular we recommend that trials of parenting interventions:

- adhere to the CONSORT guidelines for the reporting of trials;
- adopt an intention to treat approach to data analysis, in which accepted strategies for managing treatment violations and handling missing data are established and reported;
- limit the proportion of missing data, for example by minimising the amount of time between randomisation and the delivery of trial interventions, and actively managing data collection on all participants irrespective of treatment allocation or adherence; and
- include appropriate sensitivity analyses to explore the robustness of the trial conclusions to the effects of missing data.

CONCLUSION

It is of concern that recommendations for parental training programmes are still based on some trial reports that violate the main principle of ITT and others where insufficient detail is provided regarding handling of treatment violators and missing data. There is, however, some evidence that reporting standards of relevant trials are improving. Consequently, providing evidence based recommendations for parental training programmes is, at best, difficult, as robustness of the evidence is unclear. The adoption of the CONSORT guidelines, which include the use of ITT, should be adopted as a minimum standard. Researchers should design trials that reflect the socially bound nature of parenting programmes and thereby the everyday challenges faced by practitioners delivering services. As such, strategies that limit the amount of missing data should be developed and reported a priori, as should methods for handling treatment violations and missing data in the analyses.

ACKNOWLEDGEMENTS

Anna Hart, Professor Sarah Cowley, and journal reviewers are thanked for their constructive comments on earlier manuscript drafts.

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Funding: none.

Competing interests: KW contributed to the preparation of a submission to the National Institute for Health and Clinical Excellence appraisal of parenting research for the Community Practitioners and Health Visitors Association.

REFERENCES

- 1 Hill Z, Kirkwood B, Edmond K. *Family and community practices that promote child survival, growth and development*, <http://www.who.int/child-adolescent-health/publications/pubCNH.htm>.
- 2 Whittaker K, Cowley S. Parenting support: where does it fit with public health roles? *Community Practitioner* 2003;**76**:100–3.
- 3 Department for Education and Skills. *Every child matters: changes for children and young people*. Nottingham: DFES Publications, 2004.
- 4 Administration for Children and Families. Head Start Bureau. <http://www.acf.hhs.gov/programs/hsb/index.htm>.
- 5 Department of Health, Department for Education and Skills. *National Service Framework for Children, Young People and Maternity Services. Core Standards*. London: Department of Health, 2004.
- 6 HM Treasury. *Choice for parents, the best start for children: a ten year strategy for childcare*. London: HMSO, 2004.
- 7 Quinton D. *Supporting parents. Messages from research*. London: Jessica Kingsley Publishers, 2004.
- 8 National Institute for Health and Clinical Excellence. *Conduct disorder in children – parent-training/education programmes*, <http://www.nice.org.uk>.
- 9 Respect Task Force. *The Respect Action Plan*. <http://www.respect.gov.uk/index.html>.
- 10 Department of Health. *The new NHS. Modern and dependable*. London: Department of Health, 1997.
- 11 Gray JAM. *Evidence-based healthcare. How to make health policy and management decisions*. 2nd ed. Edinburgh: Churchill Livingstone, 2001.
- 12 Sackett DL, Straus SE, Richardson WS, *et al*. *Evidence-based medicine. how to practice and teach EBM*. 2nd ed. Edinburgh: Churchill Livingstone, 2000.
- 13 Rychetnik L, Frommer M, Have P, *et al*. A. Criteria for evaluating evidence on public health interventions. *J Epidemiol Community Health* 2002;**56**:119–27.
- 14 Nutbeam D. Oakley's case for using randomised controlled trials is misleading. *BMJ* 1999;**318**:944.
- 15 Wolff N. Randomised trials of socially complex interventions: promise or peril? *J Health Serv Res Policy* 2001;**6**:123–6.
- 16 Lindsay B. Randomized controlled trials of socially complex nursing interventions: creating bias and unreliability? *J Adv Nurs* 2004;**45**:84–94.
- 17 Medical Research Council. *A framework for development and evaluation of RCTs for complex interventions to improve health*. London: Medical Research Council, 2000.
- 18 Schwartz D, Lellouch J. Explanatory and pragmatic attitudes in clinical trials. *J Chronic Disab* 1967;**20**:637–48.
- 19 Armitage P. Attitudes in clinical trials. *Stat Med* 1998;**17**:2675–83.
- 20 Begg C, Cho M, Eastwood S, *et al*. Improving the quality of reporting of randomized controlled trials. The CONSORT statement. *JAMA* 1996;**276**:637–9.
- 21 Moher D, Schulz KF, Altman DG. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomized trials. *Ann Intern Med* 2001;**134**:657–62.
- 22 Ruiz-Canela M, Martinez-Gonzalez MA, Irala-Estevéz J. Intention to treat analysis is related to methodological quality. *BMJ* 2000;**320**:1007–8.
- 23 Hollis S, Campbell F. What is meant by intention to treat analysis? Survey of published randomised controlled trials. *BMJ* 1999;**319**:670–4.
- 24 Bradford Hill A. *Principles of medical statistics*. 7th ed. London: Lancet, 1961.
- 25 Lewis JA. Statistical issues in the regulation of medicines. *Stat Med* 1995;**14**:127–36.
- 26 Fisher ID, Dixon DO, Herson J, *et al*. Intention to treat in clinical trials. In: Peace KE, ed. *Statistical issues in drug research and development*. New York: Marcel Dekker, 1990:331–50.
- 27 Matthews JNS. *An introduction to randomized controlled clinical trials*. London: Arnold, 2000.
- 28 Altman DG, Schulz KF, Moher D, *et al*. The revised CONSORT statement for reporting randomized trials: explanation and elaboration. *Ann Intern Med* 2001;**134**:663–94.
- 29 Lachin JM. Statistical considerations in the intention-to-treat principle. *Control Clin Trials* 2000;**21**:167–89.
- 30 Verbeke G, Molenberghs G, Bijlens L, *et al*. *Linear mixed models in practice*. New York: Springer, 1997.
- 31 Mallinckrodt CH, Clark WS, David SR. Accounting for dropout bias using mixed-effects models. *J Biopharm Stat* 2001;**11**:9–21.
- 32 Mallinckrodt CH, Sanger TM, Dubé S, *et al*. Assessing and interpreting treatment effects in longitudinal clinical trials with missing data. *Biol Psychiatry* 2003;**53**:754–60.
- 33 Gadbury GL, Coffey CS, Allison DB. Modern statistical methods for handling missing repeated measurement in obesity trial data: beyond LOCF. *Obes Rev* 2003;**4**:175–84.
- 34 National Health Service Centre for Reviews and Dissemination. *Undertaking systematic reviews of research on effectiveness: CRD guidance for those carrying out or commissioning reviews*. University of York, York: NHS CRD, 1996.
- 35 Barlow J, Coren E, Stewart Brown SSB. Parent-training programmes for improving maternal psychosocial health. *Cochrane Library*. Issue 4. Oxford: Update Software, 2003.

- 36 **Coren E**, Barlow J. Individual and group-based parenting programmes for improving psychosocial outcomes for teenage parents and their children. *Cochrane Library*. Issue 3. Oxford: Update Software, 2001.
- 37 **Anastopoulos AD**, Shelton TL, DuPaul, et al. Parent training for attention-deficit hyperactivity disorder: its impact on parent functioning. *J Abnorm Child Psychol* 1993;**21**:581-96.
- 38 **Black MM**, Teti LO. Promoting mealtime communication between adolescent mothers and their infants through videotape. *Pediatrics* 1997;**99**:432-7.
- 39 **Blakemore B**, Shindler S, Conte RA. A problem solving training program for parents of children with attention-deficit hyperactivity disorder. *Can J Sch Psychol* 1993;**9**:66-85.
- 40 **Cunningham CE**, Bremner R, Boyle M. Large group community-based parenting programs for families of preschoolers at risk for disruptive behaviour disorders: utilization, cost effectiveness, and outcome. *J Child Psychol Psychiatry* 1995;**36**:1141-59.
- 41 **Gammon EA**, Rose SD. The coping skills training program for parents of children with developmental disabilities: An experimental evaluation. *Res Soc Work Pract* 1991;**1**:244-56.
- 42 **Greaves D**. The effect of rational-emotive parent education on the stress of mothers of young children with downs syndrome. *Journal of Rational-Emotive and Cognitive Behaviour Therapy* 1997;**15**:249-67.
- 43 **Gross D**, Fogg L, Tucker S. The efficacy of parent training for promoting positive parent-toddler relationships. *Res Nurs Health* 1995;**18**:489-99.
- 44 **Irvine AB**, Biglan A, Smolkowski K, et al. The effectiveness of a parenting skills program for parents of middle school students in small communities. *J Consult Clin Psychol* 1999;**67**:811-25.
- 45 **Joyce MR**. Emotional relief for parents: Is rational-emotive parent education effective? *Journal of Rational-Emotive and Cognitive Behaviour Therapy* 1995;**13**:55-75.
- 46 **Koniak-Griffin D**, Verzemnieks I, Cahill D. Using Videotape instruction and feedback to improve adolescents' mothering behaviors. *J Adolesc Health* 1992;**13**:570-5.
- 47 **Laggas AM**, Gordon D. Use of an interactive laserdisc parent training program with teenage parents. *Child Fam Behav Ther* 1999;**21**:19-37.
- 48 **McGillicuddy NB**, Rychtarik RG, Duquette JA, et al. Development of a skill training program for parents of substance-abusing adolescents. *J Subst Abuse Treat* 2002;**20**:59-68.
- 49 **Mullin E**, Quigley K, Glanville B. A controlled evaluation of the impact of a parenting training programme on child behaviour and mothers' general well-being. *Couns Psychol Q* 1994;**7**:167-79.
- 50 **Nicholson B**, Anderson M, Fox R, et al. One family at a time: a prevention program for at-risk parents. *J Couns Devel* 2002;**80**:362-71.
- 51 **Nixon CD**, Singer GHS. Group cognitive-behavioral treatment for excessive parental self-blame and guilt. *Am J Ment Retard* 1993;**97**:665-72.
- 52 **Odom SE**. Effects of an educational intervention on mothers of male Children with attention deficit hyperactivity disorder. *J Comm Health Nurs* 1996;**13**:207-20.
- 53 **Patterson J**, Barlow J, Mockford C, et al. Improving mental health through parenting programmes: block randomised controlled trial. *Arch Dis Child* 2002;**87**:472-7.
- 54 **Pisterman S**, Firestone P, McGrath P, et al. The effects of parenting training on parenting stress and sense of competence. *Can J Behav Sci* 1992;**24**:41-58.
- 55 **Pisterman S**, Firestone P, McGrath P, et al. The role of parent training in treatment of preschoolers with ADHD. *Am J Orthopsychiatry* 1992;**62**:397-408.
- 56 **Schultz CLF**, Bruce EJ, Carey LB, et al. Psychoeducational support for parents of children with intellectual disability: an outcome study. *International Journal of Disability, Development and Education* 1993;**40**:205-16.
- 57 **Scott MJ**, Stradling SG. Evaluation of group programme for parents of problem children. *Behav Psychother* 1987;**15**:224-39.
- 58 **Sheeber LB**, Johnson JH. Evaluation of a temperament-focused, parent-training program. *J Clin Child Psychol* 1994;**23**:249-59.
- 59 **Sirbu W**, Cotler S, Jason LA. Primary prevention: teaching parents behavioral child rearing skills. *Fam Ther* 1978;**5**:163-70.
- 60 **Spaccarelli S**, Cotler S, Penman D. Problem-solving skills training as a supplement to behavioral parent training. *Cognit Ther Res* 1992;**16**:1-18.
- 61 **Taylor TK**, Schmidt F, Pepler D, et al. A comparison of eclectic treatment with Webster-Stratton's parents and children series in a children's mental health center: a randomized controlled trial. *Behav Ther* 1998;**29**:221-40.
- 62 **Truss CV**, Benson JB, Hirst BA, et al. Parent training in preprimary competence. Annual convention of the American Psychological Association, California, 26 Aug, 1977.
- 63 **Van Wyk JD**, Eoff ME, Heyns PM. The evaluation of an integrated parent-training program. *J Soc Psychol* 1983;**121**:273-81.
- 64 **Webster-Stratton C**, Kolacoff M, Hollinsworth T. Self-administered videotape therapy for families with conduct-problem children: comparison with two cost-effective treatments and a control group. *J Consult Clin Psychol* 1988;**56**:558-66.
- 65 **Wolfson A**, Lacks P, Futterman A. Effects of parent training on infant sleeping patterns, parents' stress, and perceived parental competence. *J Consult Clin Psychol* 1992;**60**:41-8.
- 66 **Zimmerman TS**, Jacobsen RB, Macintyre M, et al. Solution-focused parenting groups: an empirical study. *J Syst Ther* 1996;**15**:12-25.
- 67 **Smith PJ**, Moffatt ME, Gelskey SC, et al. Are community health interventions evaluated appropriately? A review of six journals. *J Clin Epidemiol* 1997;**50**:137-46.
- 68 **The CONSORT Group**. CONSORT Supporters. <http://www.consort-statement.org/>.
- 69 **Dittmann M**. Guidelines seek to prevent bias in reporting of randomized trials. *Monitor Psychol* 2004;**35**:20.
- 70 **Coyne JC**, Cook JM, Palmer SC, et al. Clarification of clinical trial standards. *Monitor Psychol* 2004;**35**:4.
- 71 **Stinson JN**, McGrath PJ, Yamada JT. Clinical trials in the Journal of Pediatric Psychology: applying the CONSORT statement. *J Pediatr Psychol* 2003;**28**:159-67.
- 72 **Trudeau KJ**, Davidson K. A CONSORT primer. Outlook, quarterly newsletter of the Society of Behavioral Medicine. http://www.sbm.org/pubs/outlook/assets/pdf/2002_winter.pdf.
- 73 **McGrath PJ**, Stinson J, Davidson K. The Journal of Pediatric Psychology should adopt the CONSORT statement as a way of improving the evidence base in pediatric psychology. *J Pediatr Psychol* 2003;**28**:169-71.
- 74 **Fergusson D**, Aaron SD, Guyatt G, et al. Post-randomisation exclusions: the intention to treat principle and excluding patients from analysis. *BMJ* 2002;**325**:652-4.
- 75 **ICH**. ICH harmonised tripartite guideline: statistical principles for clinical trials (E9). Section 5.2.1 full analysis set. <http://www.ich.org/cache/compo/276-254-1.html>.
- 76 **Shih WJ**. Problems in dealing with missing data and informative censoring in clinical trials. Current controlled trials in cardiovascular medicine. <http://cvm.controlled-trials.com/content/3/1/4>.
- 77 **ICH**. ICH harmonised tripartite guideline: general considerations for clinical trials (E8). Section 3.2.2 design. <http://www.ich.org/cache/compo/276-254-1.html>.
- 78 **Montori VM**, Guyatt GH. Intention-to-treat principle. *CMAJ* 2001;**165**:1339-41.
- 79 **Schulz KM**, Grimes DA, Altman DG, et al. Blinding and exclusions after allocation in randomised controlled trials: survey of published parallel group trials in obstetrics and gynaecology. *BMJ* 1996;**312**:742-4.