Please cite this article as:

Heyvaert, M., Saenen, L., Maes, B., & Onghena, P. (2014). Systematic review of restraint interventions for challenging behaviour among persons with intellectual disabilities: Focus on effectiveness in single-case experiments. *Journal of Applied Research in Intellectual Disabilities*, 27, 493-590. doi:10.1111/jar.12094

Systematic review of restraint interventions for challenging behaviour among persons with intellectual disabilities: Focus on effectiveness in single-case experiments

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Abstract

Background: This article is the first in a two-part series: we focus on the effectiveness of restraint interventions (RIs) for reducing challenging behaviour (CB) among persons with intellectual disabilities (ID) in this first article. In the second article we focus on experiences with RIs for CB among people with ID.

Methods: A mixed methods research synthesis involving statistical meta-analysis and qualitative meta-synthesis techniques was applied to synthesize 76 retrieved articles. This first article reports on the meta-analysis of 59 single-case experiments (SCEs) on effectiveness of RIs for CB among people with ID.

Results and Conclusions: The RIs reported on in the SCEs were on average highly effective in reducing CB for people with ID, and this reduction in CB was statistically significant. However, the effects vary significantly over the included participants, and the published data and reported outcomes are rather unrepresentative of the everyday use of RIs among persons with ID.

Keywords: Single-case studies, Meta-analysis, Hierarchical linear model, Restraint, Challenging behaviour, Problem behaviour

Systematic review of restraint interventions for challenging behaviour among persons with intellectual disabilities: Focus on effectiveness

Introduction

Challenging behaviours (CBs) are prevalent among people with intellectual disabilities (ID) (Emerson et al. 2001, Holden & Gitlesen 2006, Lowe et al. 2007). Since CB is associated with negative outcomes for the persons with ID and their direct environment (e.g., increased risks of physical harm, of social exclusion, of reduced quality of life, of stress, and of costly care), divergent proactive and reactive interventions are applied to reduce CB. Restraint interventions (RIs) such as physical restraint, mechanical restraint, and environmental restraint are often used as reactive behaviour management strategies to warrant a safe and efficient management of CB among persons with ID (Adams & Allen 2001, Allen et al. 2009, Harris 1996, Jones et al. 2007, Luiselli 2009, Sturmey 2009). Due to several ethical issues (RIs conflict with certain values and ethical standards), lawfulness issues (RIs are only rendered lawful under specific conditions), and effectiveness issues (RIs can provoke additional CB, RIs can maintain CB when they function as reinforcement) issues, their use is controversial (Harris 1996, Luiselli 2009). Consequently, several recent papers call for safely reducing RIs among persons with ID (e.g., Deveau & McDonnell 2009, Luiselli 2009, Sturmey 2009, Williams 2010, Williams & Grossett 2011). However, since these interventions are still often used in the management of CB among persons with ID (e.g., Adams & Allen 2001, Allen et al. 2006, Baker & Bissmire 2000, Deveau & McGill 2009, Emerson et al. 2000, Jones et al. 2007, McGill et al. 2009, Sturmey 1999), and since they might be appropriate under certain circumstances (Department of Health 2002), it is of major importance to systematically summarize the existing research on the topic in order to accurately inform policy and caregivers.

Within the present evidence-based practice movement, researchers and practitioners increasingly rely on statistical meta-analyses and qualitative meta-syntheses to render guidelines for best practice (Beretvas & Chung 2008, Finfgeld 2003, Shadish & Rindskopf 2007). Benefits of qualitative meta-syntheses over single primary studies include containing and managing the

information explosion on a certain research topic, addressing the problem of knowledge fragmentation, identifying knowledge gaps and omissions, advancing theory development, and stimulating evidence-based practice and policy (Estabrooks *et al.* 1994, Finfgeld 2003, Jensen & Allen 1996, Major & Savin-Baden 2010, Sandelowski *et al.* 1997, Walsh & Downe 2005). The advantages of statistical meta-analytic research over single primary studies have also been widely documented and include: a higher statistical power to detect effects, more accurate effect size estimations, the ability to make more convincing generalizations to a larger population, and the ability to identify sources of heterogeneity and to test moderators to explain detected between-study variation (Borenstein *et al.* 2009, Cooper 2010, Cooper *et al.* 2009, Ellis 2010, Hartung *et al.* 2008, Kulinskaya *et al.* 2008, Lapan & Quartaroli 2009, Lipsey & Wilson 2001).

Although recently some primary studies on the *views, emotions, acceptability*, and/or *perspectives* of carers and/or persons with ID concerning RIs for CB were published (e.g., Cunningham *et al.* 2003, Dagnan & Weston 2006, Elford *et al.* 2010, Fish & Culshaw 2005, Foxx *et al.* 1996, Hawkins *et al.* 2005, Jones & Kroese 2007 2008, MacDonald *et al.* 2011, McDonnell & Sturmey 2000, Ravoux *et al.* 2012, Sequeira & Halstead 2001), so far no review systematically summarized their findings. Furthermore, even though there exists a large amount of recent single-case experimental research that evaluates the effectiveness of RIs for CB among persons with ID (e.g., see publications in Journal of Applied Behavior Analysis and Behavioral Interventions), only one older effectiveness review has been written on the topic (Harris 1996). However, this review was not a systematic review (see Higgins & Green 2008) nor did it apply statistical meta-analytic techniques to summarize the existing research on the effectiveness of these interventions. We did not find any group-comparison studies that evaluate the effectiveness of RIs for CB among persons with ID.

In order to fill these knowledge gaps, we will conduct a systematic review of experiences- and effectiveness-studies on RIs for CB among persons with ID. Retrieved 'qualitative' and 'quantitative' studies will be systematically summarized within a mixed methods research synthesis framework (Harden & Thomas 2010, Heyvaert *et al.* 2011 2013a 2013b, Sandelowski *et al.* 2006), involving systematic review techniques, statistical meta-analysis techniques, and qualitative meta-synthesis

techniques. Although it is sometimes possible to present mixed methods findings in a *single* paper, presenting the findings in *separate* papers is considered a very beneficial approach (Creswell & Tashakkori 2007, Stange *et al.* 2006). If the findings are reported in separate papers a more focused presentation and discussion of the methods and results can be provided. However, it is recommended that in the discussion the findings of one article are interpreted in light of the other article (Stange *et al.* 2006).

This article is the first in a two-part series. We focus on the effectiveness of RIs for reducing CB in this first article. We include single-case experiments (SCEs) reporting on effectiveness of RIs for CB among people with ID. In an SCE usually one person is studied: there is a manipulation of the independent variable(s) (i.e., experimental control) and the dependent variable is repeatedly measured under different levels of the independent variable for that person (cf. Onghena 2005). In comparison to the group-comparison design, some advantages of the SCE design are its focus on the individual aiming at in-depth insight into the behaviour of a single case, the study of behaviour evolution through a large number of repeated observations, and its cost-effective approach (Heyvaert *et al.* 2012, Horner *et al.* 2005, Van den Noortgate & Onghena 2007). We use statistical meta-analytic techniques to summarize the SCEs. By providing information about the overall effect and about the effects for the individual participants, a meta-analysis of SCEs combines the strengths of group-comparison studies and SCEs (cf. Van den Noortgate & Onghena 2003).

In the second article (Heyvaert *et al.* 2014) we focus on experiences with RIs for CB among people with ID. It is our intent that both papers are considered together. The overall systematic search process that is described below was aimed at retrieving effectiveness - as well as experiences-articles. Afterwards, these effectiveness- and experiences-articles were separately analysed. At the end of this first article we discuss the findings relating to the effectiveness of RIs for reducing CB. In the discussion of the second article (Heyvaert *et al.* 2014) we confront and integrate the findings of both articles.

Materials and Methods

Data collection

Systematic search process. Studies were retrieved by systematically searching electronic databases, relevant journals, bibliographies of relevant articles, and citation indexes. We searched for studies published between January 1990 and September 2011, covering more than two decades of research. First, we searched eight relevant electronic databases: Academic Search Premier, Cumulative Index to Nursing and Allied Health Literature, Embase, Education Resources Information Center, Medline, PsycINFO, PubMed, and Web of Science. We used ID-related keywords (intellectual disabilit* OR developmental disabilit* OR learning disabilit* OR learning difficult* OR mental* retard*) in combination with restraint-related keywords (restraint intervention OR restraint OR immobilisation OR immobilization OR protective equipment OR protective device OR movement restriction OR movement suppression OR protective holding). Second, we conducted a hand search of 32 relevant journals: American Journal on Intellectual and Developmental Disabilities (American Journal on Mental Retardation); Behavior Modification; Behaviour Research and Therapy; Behavior Therapy; Behavioral Disorders; Behavioral Interventions; Brain and Development; British Journal of Clinical Psychology; British Journal of Learning Disabilities; Child and Family Behavior Therapy; Clinical Case Studies; Cognitive and Behavioral Practice; Disability & Rehabilitation; Exceptional Children; Intellectual and Developmental Disabilities (Mental Retardation); International Journal of Disability, Development and Education; International Journal of Rehabilitation Research; Journal of Abnormal Child Psychology; Journal of Applied Behavior Analysis; Journal of Applied Research in Intellectual Disabilities; Journal of Autism and Developmental Disorders; Journal of Behavior Therapy and Experimental Psychiatry; Journal of Clinical Child & Adolescent Psychology; Journal of Consulting and Clinical Psychology; Journal of Developmental and Physical Disabilities; Journal of Experimental Child Psychology; Journal of Intellectual and Developmental Disability; Journal of Intellectual Disabilities; Journal of Intellectual Disability Research; Journal of Positive Behavior Interventions; Journal of Special Education; and Research in Developmental Disabilities. Third, we examined the bibliographies of all the articles that were identified as relevant in the first and second

search step. Fourth, we searched for more recent studies referring to the papers identified as relevant in the three previous search steps, by consulting three citation indexes: the Arts & Humanities Citation Index, the Science Citation Index Expanded, and the Social Sciences Citation Index - all three accessed through Web of Science.

Inclusion and exclusion criteria. We aimed at retrieving studies reporting on experiences of RIs for CB among persons with ID, as well as studies reporting on effectiveness of RIs for this population. Intending to conduct a systematic review of recent literature over the last two decades, the articles had to be published between January 1990 and September 2011. Articles that were published online in that period, but not yet published in a printed format, were also included if these articles could be retrieved in full text format.

For this first article, we focus on SCEs reporting on effectiveness of RIs for CB among people with ID. An article was included when: (a) it was an SCE article describing for each participant individual characteristics and raw data points representing the level of CB under no-restraint (i.e., baseline) and restraint conditions (i.e., intervention), by intentional manipulation of the independent variable; (b) with the raw data points reported in a table or clearly pictured in a graph; and (c) with no-restraint as well as restraint conditions containing at least five data points for each participant (cf. Horner *et al.* 2005, Kratochwill *et al.* 2010, Romeiser-Logan *et al.* 2008). As a consequence of (a), articles only reporting percentages of reduction of CB, as well as articles only reporting aggregated data for multiple participants, were excluded from the meta-analysis.

We follow the widely accepted definition of Emerson (1995) when delineating *challenging behaviour*: it is culturally abnormal behaviour of such an intensity, frequency or duration that the physical safety of the person or others is likely to be placed in serious jeopardy, or it is behaviour which is likely to seriously limit use of, or results in the person being denied access to, ordinary community facilities. Restraint interventions are defined as interventions responding to CB which involve the limitation or restriction of movement or mobility. Based on the editorials and review-papers of Harris (1996), Jones *et al.* (2007), Luiselli (2009), and Sturmey (2009), we identified three broad categories of RIs: personal restraint, mechanical restraint, and environmental restraint. Personal

restraint, also called physical restraint or manual restraint, involves direct physical contact (i.e., force or pressure) between a person with CB and at least one other person in order to prevent or restrict the CB. Mechanical restraint concerns using materials or equipment to prevent or decrease CB. Examples are arm splints, belts, harnesses, helmets, masks, mittens, specially adapted clothing, ties, and wrist weights. Environmental restraint involves using material barriers (e.g., locked doors) to restrict CB. We did not include psychotropic medication use that can restrict free movement (i.e., chemical restraint).

We excluded articles reporting on natural therapeutic holding interventions (i.e., non-punitive and non-aversive alternatives to RIs, using touch as a therapeutic medium; Stirling 1998, Stirling & McHugh 1997), since the authors state that these interventions cannot be regarded as RIs. Furthermore, we excluded articles on other interventions than RIs for CB among persons with ID but that describe in their results/discussion sections that the use of RIs decreased through the use of these *other* interventions, and that were on that account retrieved through the electronic databases search. Finally, according to Emerson's (1995) definition of CB as *culturally abnormal* behaviour, we excluded articles on the use of RIs for behaviour that is rather *normal* given specific circumstances (e.g., when visiting a dentist).

Study retrieval. The search retrieved 76 unique articles that answered our inclusion criteria: 17 articles on the experiences of RIs for CB among persons with ID, and 59 SCE articles on the effectiveness of RIs. The search of the eight electronic databases retrieved 563 unique articles, from which 20 SCE articles met our inclusion criteria. Additionally, the manual search of the 32 journals pointed us to 38 other SCE articles that met our criteria. Searching the bibliographical lists of all included articles through steps one and two identified no other relevant SCE studies. By consulting the three citation indexes on the articles included through steps one, two, and three, we additionally could include one SCE article. The 59 included SCE articles are marked (*) in the reference list.

Data analysis

Treatment effectiveness. Information on the effectiveness of the RIs was gathered from the graphs presented in the retrieved SCE articles: the raw data (i.e., XY-coordinates of all data points in

the graphs) were extracted using UnGraph Version 5 (Biosoft, 1997-2011), a software program proven to show highly valid and reliable data extraction results (Shadish *et al.* 2009).

Statistical analysis. Since design-specific issues of single-case studies (e.g., potential autocorrelation) make it undesirable to rely on general meta-analytic techniques for studies with large sample sizes, we applied statistical meta-analytic techniques developed specifically to summarize single-case studies. Several meta-analytic procedures have been developed to aggregate the findings of SCEs, including procedures for combining p values and procedures for combining effect sizes. We choose to use multilevel models to analyze the SCEs because the retrieved data show a hierarchical three-level structure: we identified 59 SCE articles (between-studies level), that describe 94 unique participants with ID and CB (between-participants level), and for each participant repeated measurements of CB are reported (within-participants level). In order to account for the possible dependency that may result from this three-level nesting, we applied an adaptation of the general hierarchical linear model that can be used for a multilevel meta-analysis of SCEs: this model is described in papers of Van den Noortgate and Onghena (2003 2008). Since the coefficient that indicates the effectiveness of an RI is equal to the difference in condition (i.e., no-restraint vs. restraint) means divided by the within-condition standard deviation in this model, it can be considered as a standardized mean difference (cf. Van den Noortgate & Onghena 2008). We used the SAS software Version 9.3 to conduct the statistical analysis of the SCEs: the SAS PROC MIXED (restricted maximum-likelihood procedure) generated estimates and tests of the overall effect, of the overall intercept, and of the covariance parameters (Littell et al. 2006, Van den Noortgate & Onghena 2003 2008).

Moderator analysis. Additionally, we studied the possible moderating effects of seven variables: five participant variables and two study variables. The five participant variables are *age* (continuous variable), *gender* (male vs. female), *ID level* (borderline, mild, moderate, severe, profound; if only a range of ID level was reported it was categorized as the lower level), the *CB type* targeted by the RI, and the *type of the RI*. Based on the CB categories used by Didden *et al.* (1997 2006) the *CB type* targeted by the RI was coded as (a) external destructive behaviour (e.g., aggression,

destructive behaviour), (b) internal maladaptive behaviour (e.g., self-injurious behaviour, stereotyped behaviour, pica), (c) socially disruptive behaviour (e.g., disruptive behaviour, inappropriate social behaviour), or (d) a combination of two or three previously mentioned categories. The *type of the RI* was coded as (a) involving personal restraint only, (b) involving mechanical restraint only, (c) involving environmental restraint only, or (d) involving combinations of the previously mentioned RI types. The two study variables are *publication year* and *methodological quality* (both continuous variables). Concerning the latter variable, the methodological quality of each SCE was coded by using the Single-case Experimental Design Scale (SCED Scale; Tate *et al.* 2008). Although there exist several other frameworks and tools for evaluating SCE studies (e.g. Horner *et al.* 2005, Reichow *et al.* 2008, Romeiser-Logan *et al.* 2008), we preferred the SCED Scale because of its good content validity and inter-rater reliability scores (Tate *et al.* 2008). We tested the moderating impact of each variable on the overall treatment effectiveness using the SAS PROC MIXED.

Reliability. The first and second author independently coded all included SCE articles (n = 59) for all included participants (n = 94). Intercoder agreement was calculated by dividing the number of agreements by the number of agreements plus disagreements. The intercoder agreement was 96.88%. Disagreements were afterwards resolved by discussion between the first and second author, and the corrected codes were used for the meta-analysis.

Results

Description of the participants, studies and effect sizes

Table 1 presents an overview of the coded variables for the 59 included studies and 94 included cases. The mean age of the participants was 24.38 (SD = 14.47; range = 3-58). There were 46 male and 48 female participants. For 82 participants the specific ID level was reported: there were 2 participants with mild, 4 with moderate, 21 with severe, and 55 with profound ID. The most often targeted CB type was internal maladaptive behaviour (for 82 of the 94 participants), and within that category for the majority of the participants only self-injurious behaviour (SIB) was treated. The most often applied RI types were personal restraint only (for 52 participants) and mechanical restraint only

(for 32 participants). For 6 participants environmental restraint only was used, and for 4 participants a combination of RIs was used (3 times a combination of personal and mechanical restraint, and 1 time a combination of personal and environmental restraint). The applied interventions are described in more detail in the last column of Table 1. Using the Single-case Experimental Design Scale, the methodological quality of the 59 articles was on average 7.31 (SD = 1.15; range = 4-9).

An effect size was calculated for each included participant. Fig. 1 displays the box and whisker diagram of the standardized random effects. The effect sizes range between 1.27 and -5.78. At the bottom of Fig.1 there is one extreme outlier, participant David described by Atcheson (2006), with an effect size of -5.78. Since this outlying effect size is not based upon incorrect values (that could lead to a distorted view of the population), the participant is not omitted from the analysis. However, as a check of the influence of this outlier on the conclusions, we will perform a sensitivity analysis (see below).

Statistical analysis

Looking at the three-level random effects regression model without moderators (i.e., Model 1 in Table 2) for the 59 SCE articles, we can conclude that the RIs are on average highly effective: in comparison to the no-restraint conditions, the level of CB is 3.16 standard deviations lower in the restraint conditions. According to the Wald test, this reduction in CB is statistically significant, Z = -7.06, p < .0001. However, considering the covariance parameter estimates, the intervention effects show to vary significantly over the participants (estimated variance of 12.21; SD = 2.50; Z = 4.89, p < .0001). The variance between studies was much smaller than the variance between participants, and was statistically not significant (estimated variance of 3.49; SD = 2.27; Z = 1.54, p = .0616).

Moderator analysis

Aiming to examine which variables can explain the variation of the intervention effectiveness over the participants, we first look at the three-level meta-analysis model including the seven moderators (i.e., Model 2 in Table 2). In Table 2, Model 2 only shows a statistically significant moderating effect for the variable Gender (Z = -2.37, p = .0178): the RIs on average turn out to be more effective for female than for male participants. No evidence was found for moderating effects of

Age (Z = -0.23, p = .8168), CB type (Z = 0.28, p = .7814), ID level (Z = -1.47, p = .1406), Restraint type (Z = 0.31, p = .7567), Publication year (Z = -0.12, p = .9082), and Study quality (Z = -0.23, p = .8147).

Second, we look at the model containing only *Gender* as moderator variable (i.e., *Model 3* in Table 2): while the expected intervention effect for male participants is -2.20 (i.e., the level of CB is 2.20 standard deviations lower in the restraint conditions in comparison to the no-restraint conditions for males), the expected effect is -4.08 for female participants (i.e., -2.20-1.88; the level of CB is 4.08 standard deviations lower in the restraint conditions in comparison to the no-restraint conditions for female participants).

Sensitivity analysis

As discussed above, the dataset includes one extreme outlier (cf. **Fig.1**). In order to study the influence of this outlier on our conclusions, we perform a sensitivity analysis: we compare the conclusions for the full dataset to the dataset without this one outlier.

By removing this outlier the overall effect only changes a little: the overall effect is -3.16 for the complete dataset and -3.18 for the dataset without the outlier. For both datasets, the Wald test shows that on average this reduction in CB is statistically significant, with respectively: Z = -7.06, p < .0001 for the complete dataset and Z = -7.07, p < .0001 for the dataset without the outlier. This means that for both datasets the interventions are on average highly effective in reducing CB. After omitting this most extreme scoring participant from the analysis, the intervention effects still vary significantly over the included participants: the estimated variance for the database without the outlier is 12.41 (SD = 2.54; Z = 4.88, p < .0001). Analogous to the complete dataset, the variance between studies for the database without the outlier is much smaller than the variance between participants, and is statistically not significant (estimated variance of 3.41; SD = 2.27; Z = 1.50, p = .0667).

For the moderator analysis too, the results and conclusions for the database without the outlier are analogous to the complete dataset: Model 2 only shows a statistically significant moderating effect for the variable Gender (Z = -2.30, p = .0213), and the RIs on average turn out to be more effective for female than for male participants. No evidence was found for moderating effects of the variables Age

(Z = -0.36, p = .7180), CB type (Z = 0.10, p = .9184), ID level (Z = -0.98, p = .3292), Restraint type (Z = 0.55, p = .5824), Publication year (Z = 0.02, p = .9844), and Study quality (Z = -0.92, p = .3564).

Finally, we look at the model containing only Gender as moderator variable (i.e., Model 3). Again the results and conclusions for the dataset without the outlier are analogous to the complete dataset: while the expected intervention effect for male participants is -2.23 (i.e., the level of CB is 2.23 standard deviations lower in the restraint conditions in comparison to the no-restraint conditions for males), the expected effect is even -4.08 for female participants (i.e., -2.23-1.85; the level of CB is 4.08 standard deviations lower in the restraint conditions in comparison to the no-restraint conditions for female participants).

Discussion

We used the hierarchical linear model to combine SCEs on the effectiveness of RIs for reducing CB among people with ID. We studied the overall effect, the differences between the included studies and participants, and the moderator effects of five participant characteristics and two study characteristics: Age, Gender, ID level, CB type, RI type, Publication year, and Methodological quality. The analyses of the 59 SCE articles show that RIs were on average highly effective in reducing CB for people with ID and that this reduction in CB was statistically significant. From the seven coded participant and study characteristics, the multilevel model only showed a statistically significant moderating effect for the variable Gender: the RIs on average were more effective for female than for male participants. We conducted a sensitivity analysis in order to study the influence of an outlying case on our results and conclusions: the conclusions regarding the main statistical analysis and the moderator analysis are the same for the full dataset as for the dataset without the one outlier.

Our meta-analysis has several strengths. This meta-analysis is the first to statistically synthesize the large amount of recently published SCE research on RIs among persons with ID. Like we mentioned in the introduction, there are several advantages of statistical meta-analytic research over single primary studies, i.e. a higher statistical power to detect effects, more accurate effect size

estimations, the ability to make more convincing generalizations to a larger population, and the ability to identify sources of heterogeneity and to test moderators to explain detected between-study and between-participant variation (Borenstein *et al.* 2009, Cooper 2010, Cooper *et al.* 2009, Ellis 2010, Hartung *et al.* 2008, Kulinskaya *et al.* 2008, Lapan & Quartaroli 2009, Lipsey & Wilson 2001). Meta-analysis is critical to cumulating research knowledge and informing policy and practice (Cooper *et al.* 2009, Hunter & Schmidt 1996, Rosenthal & DiMatteo 2001). Second, we conducted a thorough systematic search for relevant articles to be included in the meta-analysis: studies were retrieved by systematically searching 8 electronic databases, 32 relevant journals, bibliographies of relevant articles, and 3 citation indexes. Third, our search covered more than two decades of research, and included articles published to September 2011. As such this meta-analysis synthesizes the findings of current research. The publication year was taken into account as a potential moderating variable, but seemed to have no impact on the overall effect. Fourth, study quality is a potentially confounding variable. However, we coded the methodological quality of each SCE by using the SCED Scale (Tate *et al.* 2008). After testing the moderating impact of this variable on the overall treatment effectiveness using the SAS PROC MIXED we can conclude that it does not have an impact on the results.

When interpreting the results two important issues should be discussed. A first important issue is that the sample of published data and the reported outcomes in the published SCE studies seem rather unrepresentative of the everyday use of RIs among persons with ID. This is reflected in the CB type, in the purposes of RIs, and in the kinds of RIs used.

Let us first take a look at the CB type. For the participants in the SCE studies included in the meta-analysis the most often targeted CB type was internal maladaptive behaviour (for 82 of the 94 participants), and within that category for the majority of the participants only SIB was treated (cf. 3.1). However, McGill *et al.* (2009) collected data on 268 persons with whom RIs were reported to have been used and found that RIs were most likely to be used with physically aggressive behaviour. They report that 74% of the persons displaying physically aggressive behaviour required RI for decreasing that particular CB, while only 41% of the persons displaying SIB required RI for decreasing that particular CB. This discrepancy can be explained by differentiating between

"published treatment effectiveness studies on RIs" and "everyday use of RIs" among persons with ID. For the meta-analysis we retrieved published SCE studies reporting on effectiveness of RIs for reducing CB among persons with ID. In the published literature, when data are gathered on the effectiveness of RIs it is often in the context of "treatment", especially of SIB (cf. Harris 1996, Jones *et al.* 2007, Kahng *et al.* 2002, Luiselli 1992, Matson & LoVullo 2008, Van Houten *et al.* 1992). However, in their "everyday use" RIs are most often used with physically aggressive behaviour (Allen 2000, Allen *et al.* 2009, McGill *et al.* 2009, Tenneij & Koot 2008).

Additionally, we point to the validity issue of using reduction in the frequency of CB as an outcome for RIs. With regards to the RI purposes, it is important to make a distinction between the management and treatment of CB in persons with ID: treatments of CB aim to produce behavioural change that endures over time and generalises across settings, while management approaches focus on safe responding to CB when it occurs (Allen 2000). This meta-analysis includes SCE studies reporting on the effectiveness of RIs as interventions aiming at decreasing CB in persons with ID. Although almost all published SCE studies have reduction in the frequency of CB as the reported treatment outcome for RIs (see also Harris 1996), the "routine" use of RIs - i.e. the management of CB - is not typically evaluated in terms of treatment effectiveness. Accordingly, using reduction in the frequency of CB as an outcome is rather unrepresentative of the everyday management of RIs among persons with ID. RIs are increasingly seen as being designed to bring about safe, secure, and effective management of risk behaviours and are explicitly not given the intention to reduce CB (Allen et al. 2009, Lundström et al. 2011). The primary aim of using RIs among persons with ID and CB is to prevent them from harming themselves or others through their SIB or physically aggressive behaviour, and not to impact upon future probability of CB occurring (Allen et al. 2009). The reduction of CB is not a valid outcome for studying this role increasingly ascribed to RIs concerning safety and effective situational management. Alternative outcomes sensitive to safety and situational management issues are for instance improvement in quality of life.

Next, let us take a closer look at the type of RIs used. Looking at the last column of **Table 1**, it seems that the RIs reported on in the included studies are not just used for a different purpose (i.e.,

treatment rather than safe management; cf. supra) but also are largely of a different kind, when compared to the everyday use of RIs. In the included studies, the most often applied RI types were personal restraint only (for 52 participants) and mechanical restraint only (for 32 participants). For only 6 participants environmental restraint only was used, and for 4 participants a combination of RIs was used (3 times a combination of personal and mechanical restraint, and once a combination of personal and environmental restraint). However, the interventions more routinely found in service provision in reaction to CB are seclusion/isolation/confinement time-out (i.e., environmental restraint) and holding a person with force (i.e., personal restraint), and in a smaller percentage of situations mechanical restraints are used (e.g., Feldman *et al.* 2004, McGill *et al.* 2009, Tenneij & Koot 2008). Furthermore, combining several RI types is part of the everyday use of RIs, while the published studies typically report on only one kind of RI. Summarizing our discussion on this first issue, the published data are rather unrepresentative of the everyday use of RIs among persons with ID, and this is reflected in the studied CB type, in the purposes of RIs, and in the kinds of RIs used.

A second important issue that should be discussed relates to variance: the intervention effects varied significantly over the included participants. Accordingly, although we expect - based on the results of the meta-analysis - that RIs reduce CBs, this might not be true for all participants. We studied whether the variables CB type, ID level, Restraint type, Gender, Age, Publication year, and Study quality could explain this variation of intervention effectiveness over the participants. From these seven coded participant and study characteristics, the multilevel model only showed a statistically significant moderating effect for the variable Gender: the RIs on average were more effective for female than for male participants. The variation between female and male participants is interesting in two ways. First of all, it is interesting that there are more female than male participants. In Table 1 we see that of the 94 included participants, 46 are male and 48 female. For 82 of the 94 included participants information on the ID level was reported: the sample included 2 male participants with mild ID, 1 female and 3 male participants with moderate ID, 11 female and 10 male participants with severe ID, and 26 female and 29 male participants with profound ID. Based on this information, the sample does not seem representative of the population of people with severe and

profound ID presenting CB: we would expect far more males than females (e.g., McClintock *et al.* 2003). A second interesting question is why the female participants apparently respond better than the male participants (i.e., the expected intervention effect is -2.20 for males and -4.08 for females). A possible explanation is reporting bias, i.e. under-reporting of negative studies. The results on male participants who responded poorly might not have been written up.

Finally, there remains some unexplained variance. In Model 1 the intervention effects varied significantly over the participants, with an estimated variance of 12.21 (SD = 2.50; Z = 4.89, p < .0001). When Gender, Age, CB type, ID level, Restraint type, Publication year, and Study quality were taken into account in Model 2, the intervention effects still varied significantly over the participants, with the estimated variance reduced to 9.82 (SD = 2.07; Z = 4.73, p < .0001). Accordingly, there remain important inter-individual differences that cannot be explained by the seven coded variables. Further research is warranted to study this remaining between-participants variance.

This meta-analysis concerned SCE studies reporting on the effectiveness of RIs as interventions aimed at decreasing CB in persons with ID, i.e. the treatment of CB. In the second article of our two-part series (Heyvaert *et al.* 2014) we will address the views, emotions, and perspectives of carers (e.g., family, staff) and clients concerning RIs used in the management of CB among persons with ID.

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Tables

Table 1 Characteristics of the 59 included studies and 94 included cases.

Study	Publi-	Study	Case	Age	Gender	СВ	ID	Restraint	Description of the restraint procedure(s)	
	cation	quality ¹				cate-	level ³	type ⁴		
	year					gory ²				
Atcheson 2006	2006	8	_A	58	male	IMB	profound	PR only	Response blocking	
			В	45	female	IMB	profound	PR only	Response blocking	
Borrero et al. 2002	2002	6	Α	35	male	IMB	moderate	MR only	Protective equipment: baseball cap and clean gauze	
			В	8	male	IMB	profound	MR only	Protective equipment: helmet	
Cameron et al. 1996	1996	7	A	16	female	SDB		MR only	Protective equipment: helmet	
Cannella-Malone et al.	2008	7	A	10	male	IMB	profound	PR only	Hands down procedure	
2008										
Carr et al. 2002	2002	7	A	7	female	IMB		PR only	Response blocking	
Chung & Cannella-	2010	7	Α	11	female	IMB		PR only	Response blocking	
Malone 2010			В	16	female	IMB		PR only	Response blocking	
Dura 1991	1991	4	A	11	female	EDB	profound	PR only	Taking the participant down to the floor (mat)	
Fisher et al. 1996	1996	6	A	19	male	IMB	severe	PR only	Response blocking	
Fisher et al. 1997	1997	8	A	20	male	IMB	profound	MR only	Protective equipment: arm restraints	
			В	8	male	IMB	profound	MR only	Protective equipment: arm restraints	
			C	7	male	IMB	profound	MR only	Protective equipment: arm restraints	
Fisher et al. 1998	1998	8	A	7	male	EDB	moderate	PR only	Response blocking	
Fox et al. 2008	2008	4	A	28	male	EDB	mild	PR+ER	Holding the participant's arms; Exclusionary time-out	
Graff et al. 1999	1999	6	A	6	female	SDB	severe	ER only	Time-out area	
Hanley et al. 1998	1998	7	A	6	male	IMB	profound	MR only	Wrist weights	
Hanley et al. 2000	2000	8	A	36	female	IMB	profound	PR only	Response blocking	
			В	33	male	IMB	profound	PR only	Response blocking	
			С	46	male	IMB	profound	PR only	Response blocking	
Irvin et al. 1998	1998	8	A	25	female	IMB	profound	MR only	Protective equipment: arm restraints	
			В	41	female	IMB	profound	MR only	Protective equipment: arm restraints	
Jena 1995	1995	7	A		male	IMB	severe	PR only	Response blocking	
Jena 1999	1999	8	A	3	female	IMB	severe	MR only	Steel bracelet around wrist	

Kahng et al. 2001	2001	6	A	16	female	IMB	severe	MR only	Protective equipment: arm restraints	
Kelley et al. 2002	2002	7	A	10	female	SDB	severe	PR only	Response blocking	
Kerth et al. 2009	2009	7	A	16	male	IMB	severe	MR only	Protective equipment: adapted clothing	
Lalli <i>et al</i> . 1996	1996	7	A	4	female	IMB	severe	PR only	Response blocking	
Le & Smith 2002	2002	8	A	37	male	IMB	profound	MR only	Protective equipment: mittens	
			В	40	male	IMB	profound	MR only	Protective equipment: gloves	
			C	35	male	IMB	profound	MR only	Protective equipment: helmet	
LeBlanc et al. 1997	1997	6	A	4	female	IMB	severe	PR+MR	Response blocking; Arm restraints; Helmet; Face	
I 0 I 1006	1006	7	A	22	1.	D/D	f	DD1	mask attached to the helmet	
Lerman & Iwata 1996	1996	7	A	32	male	IMB	profound	PR only	Response blocking	
Lerman et al. 1997	1997	8	A	31	female	IMB	profound	PR only	Hold participant's arms to sides contingent on each occurrence of SIB	
			В	35	female	IMB	profound	PR+MR	Hold participant's arms to sides contingent on each occurrence of SIB; Collar brace	
			С	25	female	IMB	profound	PR only	Hold participant's arms to sides contingent on each occurrence of SIB	
			D	31	male	IMB	profound	PR only	Hold participant's arms to sides contingent on each occurrence of SIB	
Lerman et al. 2003	2003	9	A	18	female	IMB	severe	PR only	Response blocking	
Lindberg et al. 1999	1999	8	A	33	male	IMB	profound	PR only	Response blocking	
-			В	46	male	IMB	profound	MR only	Protective equipment: arm restraints	
Luiselli 1991	1991	5	A	22	female	IMB		MR only	Protective equipment: helmet	
Luiselli 1998	1998	8	A	15	male	IMB	severe	PR only	Hold participant's hands in his lap contingent on each occurrence of SIB	
Matson & Keyes 1990	1990	8	A	35	male	IMB	severe	PR only	Movement suppression: hold participant still with his arms extended out to the sides	
			В	39	male	COM	severe	PR only	Movement suppression: hold participant still with his arms extended out to the sides	
Mazaleski <i>et al.</i> 1994	1994	8	A	33	female	IMB	profound	MR only	Protective equipment: mittens	
	-		В	34	female	IMB	profound	MR only	Protective equipment: mittens	
THE LITERAL CONTROL OF THE PARTY OF THE PART							1		4" T	
McCord et al. 2001	2001	8			male	IMB	profound	PR only	Response blocking	
	2001	8	A B	27 38	male male	IMB IMB	profound profound	PR only PR only	Response blocking Response blocking	

			В	40	male	IMB	profound	PR only	Response blocking	
			$\frac{B}{C}$	44	male	IMB	profound	PR only	Response blocking	
McKerchar et al. 2001	2001	6	A	10	male	IMB	mild	PR+MR	Response blocking; Protective equipment: soft padded helmet	
Moore et al. 2004	2004	6	A	12	female	IMB		MR only	Protective equipment: helmet, rigid arm sleeves, shoulders and legs padded using foam, hands padded using martial arts equipment, boxing gloves, additional padding on hips	
Mueller & Kafka 2006	2006	6	A	4	female	IMB		PR only	Response blocking	
Northup et al. 1997	1997	8	A		male	COM		ER only	Exclusionary time-out	
			В	35	female	IMB	severe	ER only	Exclusionary time-out	
			С	3	female	COM	severe	ER only	Exclusionary time-out	
O'Connor et al. 2003	2003	7	A	14	male	COM	severe	ER only	Exclusionary time-out	
Piazza et al. 1998	1998	8	A	4	female	IMB	profound	PR only	Response blocking	
Rapp & Miltenberger 2000	2000	7	A	11	male	IMB	severe	PR only	Response blocking	
Rapp et al. 2000	2000	9	A	19	female	IMB	severe	MR only	Hand splint	
Rapp et al. 2001	2001	8	A	6	female	IMB		PR only	Response blocking	
Reid et al. 1993	1993	7	A	57	female	IMB	profound	PR only	Response blocking	
			В	27	female	IMB	profound	PR only	Response blocking	
Richman et al. 1998	1998	6	A	27	female	IMB	profound	PR only	Response blocking	
Roane et al. 2001	2001	9	A	23	female	IMB	profound	PR only	Hold participant's hands parallel to hips contingent on each occurrence of SIB	
			В	14	female	IMB	profound	PR only	Hold participant's hands down contingent on each occurrence of SIB	
Rolider et al. 1991	1991	7	A	24	male	COM	moderate	PR only	Movement restriction: the mediator placed his/her hand on the participant's upper back and pushed the participant forward down to the knees, so that the participant's chest rested on his own lap; The participant's arms were then placed behind his back	
Roscoe et al. 1998	1998	8	A	29	male	IMB	profound	MR only	Protective equipment: foam sleeves	
			В	35	female	IMB	profound	MR only	Protective equipment: boxing gloves	
			С	20	female	IMB	moderate	MR only	Protective equipment: latex gloves	

Sisson et al. 1993	1993	9	A	18	male	IMB	profound	PR only	Manual movement suppression
			В	10	male	IMB	profound	PR only	Hold participant's arms to sides contingent on each
							-		occurrence of SIB
Smith et al. 1992	1992	8	A		male	IMB	profound	MR only	Protective equipment: arm tubes
			В		male	IMB	profound	MR only	Protective equipment: adapted clothing
			С		male	IMB	profound	MR only	Protective equipment: adapted clothing
Smith et al. 1996	1996	6	A	32	female	IMB	profound	PR only	Response blocking
Smith et al. 1999	1999	7	A	41	female	IMB		PR only	Response blocking
Tarbox et al. 2002	2002	9	A	4	male	IMB		PR only	Response blocking
Thompson et al. 1998	1998	7	A	7	male	IMB	severe	PR only	Response blocking
Thompson et al. 1999	1999	8	A	34	male	IMB	profound	PR only	Hold participant's hands in his lap contingent on each
									occurrence of SIB
			В	43	female	IMB	profound	PR only	Hold participant's hands across chest contingent on
									each occurrence of SIB
			C	44	female	IMB	profound	PR only	Hold participant's hands across chest contingent on
									each occurrence of SIB
Toole et al. 2003	2003	7	A	15	female	COM	severe	ER only	Exclusionary time-out
Turner et al. 1996 1996 9 A 40 female IMB pr		profound	PR only	Hold participant's hands in her lap contingent on each					
									occurrence of SIB
			В	26	male	IMB	profound	PR only	Hold participant's hands in his lap contingent on each
									occurrence of SIB
			C	21	female	IMB	profound	PR only	Hold participant's hands in her lap contingent on each
									occurrence of SIB
Van Houten 1993	1993	8	A	10	male	IMB	severe	MR only	Wrist weights
Vollmer et al. 1994	1994	9	A	4	female	IMB		PR only	Response blocking
Zhou et al. 2000	2000	8	A	33	female	IMB	profound	MR only	Protective equipment: sleeves
			В	33	female	IMB	profound	MR only	Protective equipment: sleeves
			С	40	female	IMB	profound	MR only	Protective equipment: sleeves
			D	51	female	IMB	profound	MR only	Protective equipment: sleeves

Notes: CB = challenging behaviour; ID = intellectual disability

Empty cell: Information missing for this study / for this case

1: The methodological quality of the articles was coded by using the Single-case Experimental Design Scale (SCED Scale; Tate et al. 2008)

²: EDB = external destructive behaviour (e.g. aggression, destructive behaviour); IMB = internal maladaptive behaviour (e.g. self-injurious behaviour, stereotyped behaviour, pica); SDB = socially disruptive behaviour (e.g. disruptive behaviour, inappropriate social behaviour); COM = a combinations of two or three previously mentioned categories

3: If only a range of intellectual disability level was reported, it was categorized as the lower level

4: PR = personal restraint; MR = mechanical restraint; ER = environmental restraint

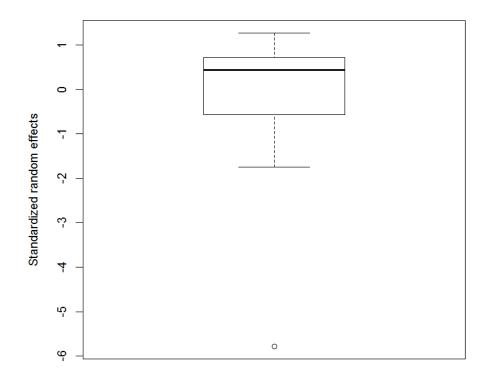
Table 2 Parameter estimates and standard errors for the multilevel meta-analysis of the 59 SCE studies on the effectiveness of restraint interventions for challenging behaviour among persons with intellectual disabilities.

	Model 1	Model 2	Model 3
Fixed effects			
Mean treatment effect	-3.16 (0.45) ***		-2.20 (0.60) ***
Moderator effect of			
Age		-0.01 (0.03)	
Gender		-1.96 (0.83) *	-1.88 (0.82) *
CB type		0.22 (0.78)	
ID level		-0.99 (0.67)	
Restraint type		0.18 (0.58)	
Publication year		-0.01 (0.11)	
Study quality		-0.11 (0.46)	
Variance of effect			
Between studies	3.49 (2.27)	2.32 (1.66)	3.05 (2.19)
Between participants	12.21 (2.50) ***	9.82 (2.07) ***	11.88 (2.45) ***
Residual variance	1.00 (0.02) ***	1.00 (0.02) ***	1.00 (0.02) ***

Notes: CB = challenging behaviour; ID = intellectual disability * = statistically significant effect: p < .05; ** = p < .01; *** = p < .001

Figures

Figure 1Box and whisker diagram of the standardized random effects for the individual participants.



Cases