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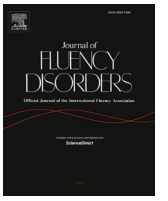

Systematic review of implementation quality of non-pharmacological stuttering intervention trials for children and adolescents

Hilde Hofslundsengen [a,*], Melanie Kirmess [b,d], Linn Stokke Guttormsen [b], Kari-Anne Bottegaard Næss [b], Elaina Kefalianos [c]

[a] Western Norway University of Applied Sciences, Faculty of Education, Arts and Sports, box 131, 6856 Sogndal, Norway
[b] University of Oslo, Department of Special Needs Education, Mail Box 1140 Blindern, 0318 Oslo, Norway
[c] University of Melbourne, Department of Audiology & Speech Pathology, Faculty of Medicine, Dentistry and Health Sciences, Level 2, 550 Swanston Street, Carlton, 3052, Australia
[d] Sunnaas Rehabilitation Hospital, Bjørnemyrveien 11, 1453 Bjørnemyr, Norway

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ABSTRACT

Purpose: This narrative systematic review in line with PRISMA guidelines aims to investigate the implementation quality of previously published group comparison clinical trials of stuttering interventions for children and adolescents (under age 18 years).
Methods: We searched for publications in the databases Eric, PsychInfo, PubMed and Web of Science using the search terms 'stutt*' or 'stamm*'and 'intervention', 'trial' or 'treatment'. We reviewed the implementation elements reported in studies and how these elements were used to report intervention outcomes.
Results: 3,017 references published between 1974–2019 were identified. All references were screened for eligibility using predefined selection criteria resulting in 21 included studies. The implementation quality details reported varied between studies. Existing studies most commonly lacked details about the support system provided to SLPs administering the interventions and monitoring of treatment fidelity both in the clinical setting and in the home environment. Support systems for participant's parents and treatment dosage were generally well reported. Dosage was the most common implementation quality element considered in analyses of treatment effect and within discussions of findings.
Conclusion: Findings highlight the need for future clinical trials of stuttering interventions to closely adhere to systematic guidelines for reporting implementation quality to ensure reliability of trial outcomes. A checklist for reporting clinical trials of non-pharmacological stuttering interventions is proposed.

1. Introduction

Developmental stuttering, also known as childhood-onset fluency (DSM 5; American Psychiatric Association, 2013), is classified as

* Corresponding author.
E-mail addresses: Hilde.hofslundsengen@hvl.no (H. Hofslundsengen), melanie.kirmess@isp.uio.no (M. Kirmess), l.s.guttormsen@isp.uio.no (L.S. Guttormsen), k.a.b.nass@isp.uio.no (K.-A.B. Næss), elaina.kefalianos@unimelb.edu.au (E. Kefalianos).

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a 'neurodevelopmental disorder' according to the International statistical classification of diseases and related health problems (11th ed.) (World Health Organization, 2018). Stuttering is described as "persistent and frequent or pervasive disruption of the rhythmic flow of speech that arises during the developmental period and is outside the limits of normal variation expected for age and level of intellectual functioning and results in reduced intelligibility and significantly affects communication" (World Health Organization, 2018, 6A01.01). Individuals who persist with stuttering may have a heightened risk of developing comorbidities such as social anxiety, depression and negative attitudes to communication (Iverach et al., 2009). It seems therefore important that children and adolescents who stutter have access to effective interventions to reduce stuttering and to minimize the potential adverse impacts of stuttering. There are currently many stuttering interventions for children and adolescents, but further clinical trials for these age groups are needed to determine what treatment is effective for whom and to address unresolved issues identified in previous trials such as large attrition rates (i.e. Trajkovski et al., 2019) and relapse from treatment (c.f. Jones et al., 2010).

Research indicates that implementation quality (i.e., training for clinicians/parents, adaptations of intervention programs, planned dosage, adherence to dosage and monitoring of sessions) is strongly associated with trial outcomes (Glenn et al., 2013; Law et al., 2012; Wilson, Lipsey, & Derzon, 2003). Evaluation of implementation quality of clinical trials is related to internal and external validity (Durlak & DuPre, 2008). Poor outcomes for a stuttering intervention may reflect poor implementation quality of the clinical trial as opposed to the intervention itself. Similarly, positive outcomes for an intervention may be generated for an ineffective intervention if implementation quality is inadequate. Implementation quality is therefore essential for the evaluation of an interventions' efficacy and for replicability.

High quality clinical trials are imperative to provide clinicians with treatment outcomes they can reliably use to make clinical judgements and to enable them to identify the benefits and limitations of different intervention approaches (Guayatt et al., 2008). Children and adolescents who stutter, their parents and speech language pathologists (SLPs) dedicate time, effort and finances to delivering stuttering intervention in order to improve the child's fluency skills and communication attitude to prevent possible future negative secondary outcomes related to stuttering. It is therefore essential from an ethical standpoint that the stuttering interventions being recommended are based on thorough research where the outcomes reported are based on high quality implementation procedures.

1.1. Evaluating implementation quality in trials

Domitrovich et al., 2008 argue that two components must be considered when evaluating implementation quality: (a) the intervention itself and (b) the support system for the intervention. The intervention refers to content-based strategies designed to achieve a specific outcome, while the support system refers to strategies used to reduce variability in the implementation quality of the intervention being evaluated. In accordance with Domitrovich et al., 2008 the intervention should ideally be protocolised: core elements (detailed instructional manuals and session plans) should be monitored to ensure standard delivery between participants, across clinic sites and/or service delivery models (mode of delivery, who is delivering the intervention, treatment fidelity and dosage); pre-intervention training should be provided to give the person delivering the intervention the necessary knowledge and skills to conduct the intervention and, training and/or mentoring should be provided throughout the intervention to the individuals involved in delivering the intervention.

One way to address these challenges in reporting intervention details is to use guidelines such as The Consolidated Standards of Reporting Trials (CONSORT; Schulz, Altman, Moher, & CONSORT Group, 2010) for overall methodology issues, or The Template for Intervention Description and Replication (TIDieR; Hoffmann et al., 2014) for implementation quality. TIDieR aims at better reporting of interventions by highlighting the following 12 items: 1) intervention name, 2) rationale for the intervention (*why*), 3) intervention materials including pre-training of the intervention providers (*what*), 4) procedures including adaptation and support systems (*what*), 5) details about the providers, including their background, training provided and competence monitored (*who*), 6) delivery modes (*how*), 7) intervention location (*where*), 8) dosage including number of sessions, duration, frequency and length (*when* and *how much*), 9) planned individualisation, 10) modification of the intervention, 11) planned fidelity and adherence and 12) actual intervention fidelity and adherence (Hoffmann et al., 2014). The TIDieR guidelines could therefore be used to systematically operationalize components related to the evaluation of implementation quality as discussed by Domitrovich et al., 2008. Together, Hoffmann et al. (2014) and Domitrovich et al., 2008 suggest a specific set of items as important aspects to code when investigating the implementation quality of clinical trials. These items could be used for future development of guidelines specific to reporting of stuttering interventions.

1.2. Methodological quality of stuttering treatment research

To date, two studies have focused on the methodological quality of randomized control trials (RCT) and quasi-experimental trials (QED) of stuttering treatment research (Nye & Hahs-Vaughn, 2011; Onslow & Lowe, 2019). In their systematic review of 23 studies, Nye and Hahs-Vaughn (2011) concluded that while overall methodological reporting was acceptable using the Downs and Black (1998) checklist, issues with external and internal validity were identified. In fact, they identified that only half of the included studies in their review provided adequate details regarding compliance with intervention. Furthermore, over a third of the included studies (35 %) did not provide explicit details about treatment setting or context which limits replicability and generalisability of findings. Nye and Hahs-Vaughn (2011) stated that the lack of detail provided about the implementation of treatment trials was problematic and made interpretation of results difficult. Recently, Onslow and Lowe (2019) proposed a set of guidelines for future clinical trials of stuttering treatment based on a published clinical trial evaluating the RESTART and Lidcombe treatment programs (de

Sonneville-Koedoot, Stolk, Rietveld, & Franken, 2015). Two of the recommendations made in these guidelines are particularly relevant to the current study's aims of investigation of implementation quality: first, "ensure that all children in a clinical trial have completed treatment" in order to ensure that "treatments are evaluated in their entireties" (Onslow & Lowe, 2019, p. 525). This allows treatments to be evaluated based on the time it takes to reduce stuttering to a predetermined level or to eliminate stuttering completely. And second, "establish treatment fidelity within and beyond the clinic" so that clinicians can ascertain whether they are able to replicate the treatment in their own clinics (Onslow & Lowe, 2019, p. 525). These guidelines underline the importance of implementation quality particularly in relation to the utility of stuttering intervention outcomes in clinical settings.

1.3. The current study

Few studies have investigated implementation quality specifically in stuttering intervention research. However, the potential risk of bias in methodology that partially overlaps with implementation quality has been discussed in systematic reviews examining the effectiveness of non-pharmacological stuttering interventions (Baxter et al., 2015; Bothe, Davidow, Bramlett, & Ingham, 2006; Nye et al., 2013). For example, Baxter et al. (2015) noted a paucity of information about the randomization procedures used. In some instances, they found that intervention was delivered to more participants than was reported, blinding of outcome assessors was not conducted, and/or findings were based on small sample sizes. Nye et al. (2013) reported inadequate treatment fidelity, observing that some studies did not specify the amount of treatment participants received thus making interpretation of results difficult.

No studies published to date have investigated the implementation quality of stuttering interventions. Coupled with the above-mentioned methodological limitations of previous clinical trials of stuttering interventions and the effect that implementation quality may have on the results of clinical trials, there is a need to examine the implementation quality of previously published trials of stuttering interventions for children and adolescents. This data could inform plans for implementation of future clinical trials of stuttering intervention. This study therefore aimed to address the following research questions:

1 What elements of implementation quality have been reported in previously published clinical trials of stuttering interventions for children and adolescents?
2 To what extent has implementation quality data been included in an outcome analysis or discussion of results in previously published clinical trials of stuttering interventions for children and adolescents?

2. Does implementation quality vary according to publication year?

In our second research question, we aimed to review to what extent previous trials had integrated implementation quality elements into their analysis of treatment effects and/or discussion of treatment outcomes. This has not been considered in previous reviews of stuttering interventions, but is an important consideration to make when determining the effectiveness of a treatment (Durlak & DuPre, 2008; Miller & Rollnick, 2014). By integrating implementation quality elements in the analyses, researchers could investigate if treatment effects vary within their study according to how treatment aspects are delivered. For example, this could be examined by comparing outcome data of all treated cases with outcome data of high-fidelity cases (i.e., cases assessed as correctly using 80–100 % of treatment strategies in fidelity coding based on monitoring of parents and/or clinicians) or comparing outcome data of the full intended-to-treat group with the outcome data of the participants who actually received the treatment (Miller & Rollnick, 2014). As most implementation quality research has been published in the last decade (Meyers, Durlak, & Wandersman, 2012), we examined, in our third research question, if year of publication was related to implementation quality.

3. Material and methods

This systematic review followed PRISMA guidelines (Moher et al., 2015) for reporting outcomes and was pre-registered in Prospero, CRD42018096410. Available from: http://www.crd.york.ac.uk/PROSPERO/display_record.php?ID=CRD42018096410. The search was conducted between 1st July and 30th August 2018 and updated in July 2019.

3.0.1. Eligibility criteria

Eligible studies had to be non-pharmacological interventions for people younger than 18 years who stutter. Eligible studies had a control condition and pre- and post-test design such as RCTs or QEDs. The control condition had to be a participant group who did not receive any intervention or receive a comparison intervention. In the case of three-armed studies, the intervention identified as the main intervention by the author(s), or when no main intervention was given, the first intervention described by the author(s) was listed as the main intervention. Clinical trials which included baseline control conditions or case studies were excluded due to lack of control group. No restrictions were set for year of publication. Only publications written in English were included.

3.0.2. Information sources and search

We searched for relevant studies in the following databases: Eric, PsychInfo, PubMed, and Web of Science. Additionally, we conducted a hand search of six journals that focus on speech language pathology and/or communication disorders (Journal of Fluency Disorders; Journal of Speech, Language, and Hearing Research; International Journal of Speech-Language Pathology; International

Journal of Language and Communication Disorders; Language, Speech and Hearing Services in Schools; Journal of Developmental and Physical Disabilities). We also searched the reference lists of previously published reviews of stuttering interventions (Baxter et al., 2015; Bothe et al., 2006; Nye et al., 2013). The search strategy focused on terms that relate to or describe stuttering intervention. In the pre-registration, the following search string was used: 'stutt*' or 'stamm*' and 'trial' or 'treatment' or 'intervention' or 'RCT' or 'effect' or 'improve' or 'training' or 'enhan*' or 'evaluate' or 'compare' or 'comparison' or 'program*' or 'teaching' or 'random' or 'evidence' or 'control' or 'efficacy'. This search initially identified more than 27,000 references in PubMed so the search string was modified. The revised search string was: 'stamm*' or 'stutt*' and 'trial' or 'treatment' or 'intervention' or 'RCT' or 'program*'. Additionally, we restricted the search to abstracts and added criteria of English language, peer reviewed, and participants under 18 years. As we wanted to investigate how implementation quality was reported in research papers, grey literature such as conference proceedings was not included. References were collected in an Endnote file and uploaded to the systematic review software DistillerSR (2008) for screening.

3.0.3. Study selection

Prior to screening all duplicates were removed. The titles and abstracts of retrieved studies were screened by the first and last

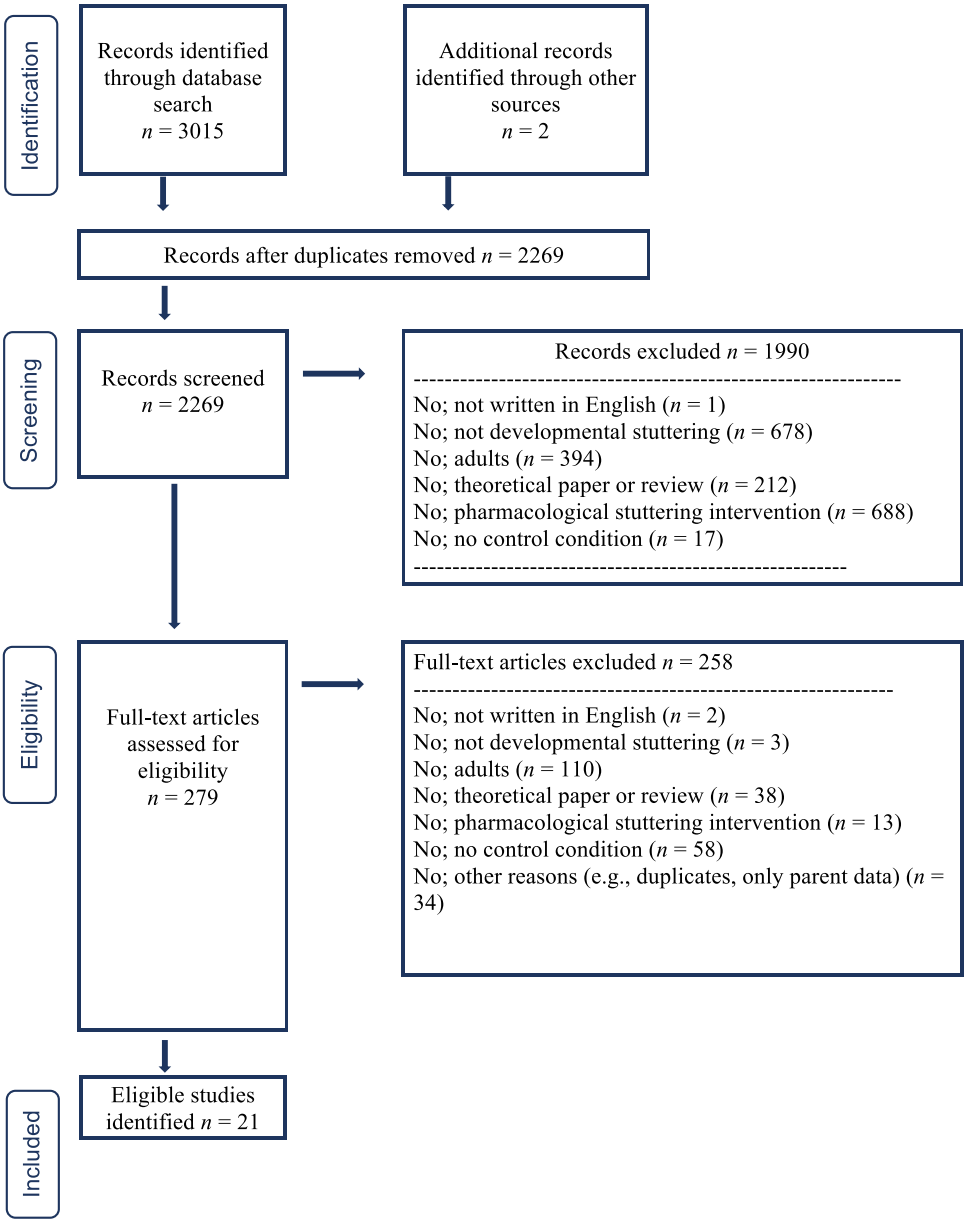

Fig. 1. Flow chart of screening process to identify eligible studies.

authors to identify studies that potentially met the inclusion criteria. The full text of these potentially eligible studies were then retrieved and independently assessed for eligibility by the authors. Any disagreements regarding the eligibility of a study were resolved through discussion (with a third team member where necessary).

3.0.4. Data collection process and data items

A standardized, pre-piloted form was used to extract required data from eligible studies.

Based on study description the following data was extracted from each eligible study: author names, sample size at randomization, attrition rate, participant age range at recruitment, program name, programs core component, direct or indirect intervention strategies, control conditions, study design (e.g., RCT or QED), if and how implementation quality elements were used for calculation of outcome measures and in discussion of the results.

Implementation quality was evaluated based on the following primary outcome measures:

Table 1
Descriptive overview of the 21 included studies.

Author	Year	Age (years)*	Sample size (attrition)	Program	Core component
QED studies					
Craig et al. (1996)	1996	9 to 14	101 (4)	Intensive smooth speech; intensive EMG; home based smooth speech	Enhance airflow when speaking with easy, relaxed diaphragmatic breathing
Donaghy et al. (2015)	2015	2;10 to 5;10	38 (4)	LP without request for self-correction of stuttered speech	VC but no request for self-correction of stuttered speech
Franken, Kielstra-Van der Schalk, and Boelens (2005)	2005	4;2–4;3**	30 (7)	Restart DCM	Environmental adjustment to parent speech; interaction time
Harris, Onslow, Packman, Harrison, and Menzies (2002)	2002	2 to 4;11	29 (6)	LP in 12 weeks	VC
Harrison, Onslow, and Menzies (2004)	2004	2 to 5;11	46 (8)	LP parental verbal contingencies and/or severity rating	VC and/or severity rating
Millard, Edwards, and Cook (2009)	2009	3;07 to 4;11	14 (8)	Palin PCIT	Interaction strategies between parent and child
Onslow, Andrews, and Lincoln (1994)	1994	2;11to 4;4	40 (17)	The operant program	VC, stuttering awareness; fluency shaping
Prins and Nichols (1974)	1974	11 to 15	32 (0)	Non-residential program	Stuttering modification with stuttering easily, syllable prolongation; slide response
Prins (1976)	1976	10 to 15	17 (0)	Modified speech modification program	Stuttering awareness; speech modification
Riley and Ingham (2000)	2000	3.8 to 8.4	12 (0)	Speech motor training	Speech motor training using syllable sequences, co-articulation; positive reinforcement
Ryan and van Kirk Ryan (1995)	1995	7 to 17	24 (4)	Delayed auditory feedback; gradual increase in length and complexity of utterance	Prolonged speech with DAF equipment
Smits-Bandstra and Yovetich (2003)	2003	9 to 12	5 (0)	Cognitive behavioural therapy	Fluency enhancing; cognitive techniques
RCT studies					
Arnott et al. (2014)	2014	3 to 5;11	54 (10)	LP	VC
Bridgman, Onslow, O'Brian, Jones, and Block (2016)	2016	3 to 5;11	49 (12)	LP webcam	VC
de Sonneville-Koedoot et al. (2015)	2015	3 to 6	199 (22)	Restart DCM	Decrease motoric, linguistic, emotional or cognitive demands; training fluency
Druker, Mazzucchelli, and Beilby (2019)	2019	3 to 6	28 (1)	Beilby Stuttering Therapy; The Curtin Early Childhood Stuttering Resilience Program	Response contingent principles, environmental adjustment; behavioural management
Jones et al. (2005)	2005	3 to 6	54 (7)	LP	VC
Lattermann, Eurler, and Neumann (2008)	2008	3 to 5;11	46 (1)	LP	VC
Lewis, Packman, Onslow, Simpson, and Jones (2008)	2008	3 to 6	22 (4)	LP telehealth	VC
Nejati, Pouretemad, and Bahrami (2013)	2013	12**	30 (0)	Neurocognitive Joyful Attentive training intervention	Selective attention; executive training
Trajkovski et al. (2019)	2019	2;6 to 5;11	91 (34)	Westmead Program	Syllable timed speech

NB. Table content is based on data provided in each cited paper. The same intervention program may therefore be named and/or described differently across publications. RCT = randomized controlled trial; QED = quasi experimental design; LP = Lidcombe Program; Restart DCM = Restart Demands and Capacities Model; Palin PCIT = Palin Parent Child Interaction Therapy; VC = verbal contingencies; * Age as reported by authors; **mean age.

- Description of the intervention protocol and/or reference to an intervention manual
- Delivery system of the intervention, including support provided to the person(s) who delivered the intervention
- Intervention dosage specifications including a) the number of clinical visits required; (b) the length of each clinical visit; (c) the frequency of clinical visits; (d) the number of intervention sessions at home required; (e) the length of each intervention session at home; (f) the frequency of intervention sessions at home;
- Intervention fidelity variables for clinicians and/or participants and/or parents of participants: adherence dosage and adaptation of program;
- Details regarding monitoring the intervention in the clinic and/or at home

We also investigated if any implementation quality elements were included in the evaluation of treatment outcomes and/or considered in the discussion of the results. To investigate if year of publication was associated with implementation quality, we calculated an overall implementation quality score. This score was calculated from the following four aspects of implementation quality (maximum score = 18):

- support system: (a) clinician and (b) parental training: not reported = 0, unclear = 1, reported = 2
- prescribed treatment dosage: (a) in the clinic and (b) at home: not reported = 0, reported one dosage detail (length, frequency or number of sessions) = 1, reported two dosage details = 2, reported three dosage details = 3
- treatment adherence: (a) in the clinic and (b) at home: not reported = 0, unclear = 1, reported = 2
- monitoring of intervention: (a) in the clinic and (b) at home: not reported = 0, unclear = 1, reported = 2

Three of the studies did not deliver intervention at home. This was adjusted for in our calculations, by using maximum score = 11 (only dosage, treatment adherence and monitoring at the clinic).

Data was analysed descriptively using frequencies and percentages. To answer the third question about relation between studies publication year and implementation quality, we used Spearman rank correlation in SPSS 27 (IBM Corp., 2021).

4. Results

Fig. 1 summarises the process of screening publications for inclusion in the study. 3,015 records were identified in the initial search. All references were double screened and inter-rater reliability at the full-text screening level was strong (kappa 0.89) (Cohen, 1960). We excluded 258 studies at full-text screening level, mostly due to participants being over 18 years of age or no control condition being used. In line with recommendations (Cochrane 4.6.3, 2011) we have provided reasons for excluding some clinical trials of stuttering interventions in *Characteristics of excluded studies* (see Appendix A). Twenty-one studies were identified as eligible for inclusion and all included studies were independently double coded, and inter-rater reliability was strong (kappa 0.84). All conflicts were resolved through discussion until agreement was established.

After coding the 21 included studies, the relevant data to answer our research questions was extracted. Table 1 presents the main characteristics of the included studies. Of the 21 studies, nine used a RCT design and the remaining 12 studies used a quasi-experimental design. All the included studies were published between 1974 and 2019. Five of the studies were published before 1999, nine studies were published between 2000–2009, and the most recent seven studies were published after 2010.

The stuttering intervention program investigated most frequently amongst the included studies was the Lidcombe Program. Specifically, eight studies (38 %) evaluated the Lidcombe Program as the main intervention program, two (9 %) evaluated the RESTART Demands and Capacities Model Program, and two (9 %) evaluated a speech modification program. The nine remaining studies evaluated Palin Parent Child Interaction Therapy, the Westmead Program, the Beilby Stuttering Therapy, delayed auditory feedback, or intensive smooth speech (for details see Table 1).

Participants were younger than 6 years of age at recruitment in 13 studies (62 %). Age as reported by authors is shown in Table 1. Across QEDs and RCTs the mean participant sample size at randomization was 46 (range: 5–199). Sixteen of the included studies (76 %) reported attrition rates. The mean attrition rate was 15 % however the reported range was wide (0 %–57 %). Cited reasons for attrition included family illness, moving to a new house, parents and/or child unwilling or unable to attend visits or make required speech recordings or preference for treatment centre closer to home.

4.1. Elements of implementation quality

Elements of implementation quality reported in the included studies related to a) information about the intervention program and/or b) support systems provided, intervention dosages and monitoring of the program. All included studies reported on at least one element of implementation quality. Ten of the studies (45 %) described the intervention and referred to a manual, nine (43 %) described the intervention only, and the remaining two (10 %) studies only referred to a manual. Details about intervention protocols were generally well described.

Intervention was delivered by the child's parent(s) and clinician/SLP in 18 studies. In the remaining three studies, intervention was delivered solely by the researcher/clinician. Face-to-face delivery was used in most studies ($n = 18$), while the remaining studies ($n = 3$) adopted digital service delivery modes.

As summarised in Table 2, details provided regarding the support systems available throughout trials was low. None of the studies described adaptations made to the intended intervention throughout the trial. It was unclear in 16 (76 %) studies whether the treating

clinician had been given any training prior to intervention commencing. In the remaining 5 (24 %) studies clinician training was described. Almost all the studies ($n = 17$ (of 18)) in which parents were responsible for delivering intervention to their child detailed support systems available to parents. These supports included individual training and/or workshops. Only one of the studies which required parental delivery of intervention did not provide any details regarding training and/or supports for parents.

Intervention dosage was the most commonly reported implementation quality element. Except for one study, all studies reported on at least one intended intervention dosage variable for clinical visits (length, frequency or number). Five (24 %) of the studies reported on length, frequency and number of clinical visits prescribed in their respective intervention program. Intervention dosage adherence for clinical visits was reported in 12 (57 %) of the studies. Of these studies, only one study reported adherence details for length, frequency and number of clinical visits. Nine (50 %) studies reported intended treatment dosage at home. However parental adherence to treatment dosage at home was reported to varying extents in three (17 %) studies only.

Three (14 %) studies reported that clinicians were monitored during clinical sessions. Monitoring strategies ranged from audio and/or video recordings to logs, live observation and observation through one-way mirrors. Six studies (33 %) reported monitoring intervention sessions delivered at home using audio and/or video recordings, questionnaires or parent reports.

4.2. Use of implementation quality data in analyses and discussion of outcomes

Seven studies (33 %) evaluated implementation quality data within their treatment outcomes. All seven studies focused on treatment dosage, evaluating the number of clinical visits required to reach maintenance level. None of the included studies considered monitoring strategies or adherence to treatment programs within their evaluation of treatment outcomes.

Twelve studies (57 %) included implementation quality data in their discussion of outcomes. Intervention dosage was discussed in

Table 2
Percentage of studies that reported on implementation quality variables.

Implementation quality variable	Number of studies (%)
Support system for clinician	
Training provided	5 (24 %)
Training not provided/unclear	16 (76 %)
Support system for parent*	
Training provided	17 (94 %)
Training not provided/unclear	1 (6 %)
Adaptations of intervention	
Adaptations made	0 (0 %)
Adaptations not made/unclear	21 (100 %)
Prescribed clinical visit dosage	
Length, frequency and duration reported	5 (24 %)
Length, frequency or duration reported	15 (71 %)
Unclear or no details provided	1 (5 %)
Adherence to clinical visit dosage	
Length, frequency and duration reported	1 (5 %)
Length, frequency or duration reported	11 (52 %)
Unclear or no details provided	9 (43 %)
Prescribed home intervention dosage*	
Length, frequency and duration reported	1 (5 %)
Length, frequency or duration reported	8 (45 %)
Unclear or no details provided	9 (50 %)
Adherence to home intervention dosage*	
Length, frequency and duration reported	0 (0 %)
Length, frequency or duration reported	3 (17 %)
Unclear or no details provided	15 (83 %)
Monitoring clinical visits	
Monitored	3 (14 %)
Not monitored/unclear whether visits were monitored	18 (86 %)
Monitoring home intervention sessions*	
Monitored	6 (33 %)
Not monitored/unclear whether sessions were monitored	12 (67 %)

Note: * This variable was not applicable for 3 studies that did not include home intervention sessions as part of their prescribed intervention.

all of these studies. However, eight of the twelve studies (38 %) discussed more than one implementation quality element in their findings, such as delivery ($n = 4$) and training of parents and clinicians ($n = 4$) in relation to treatment outcomes. Service delivery mode (group or individual) was considered in two studies while adaptation of intervention and monitoring strategies were not discussed in any of the included studies.

4.3. Implementation quality and year of publication

We investigated if year of publication had any impact on implementation quality elements reported. There was no significant association between year since publication and implementation quality score (rho = 0.03, $p = 0.89$). While more RCTs have been published in recent years reporting the use of implementation quality elements has not increased reliably.

5. Discussion

In the present study we reviewed the implementation quality of clinical trials of non-pharmacological stuttering interventions for children and adolescents. In general, the elements of implementation quality reported within each of the included studies and the level of detail provided about these elements varied greatly between studies. The results showed no significant relationship between recent and older studies with regards to implementation quality. These main findings are discussed below.

5.1. Elements of implementation quality

Our first research question focused on what elements of implementation quality had been reported in trials of stuttering interventions for children and adolescents. All studies reported on at least one element of implementation quality; intended treatment dosage and parent training were the most commonly reported elements. Including details about parent training may reflect the fact that parent training is a core element of many available treatment programs, particularly for younger children, making it imperative to include in descriptions of treatments. Similarly, intended treatment dosage is arguably a more straightforward element to document relative to other elements of implementation quality.

Overall, details regarding the intervention program itself were provided to varying extents across all included studies using a treatment manual/protocol. Most studies did not however detail whether any deviations from protocols were made once trials had commenced. This is particularly pertinent for many of the available stuttering treatment programs, as core components of treatment protocols can vary across children and adolescents according to their treatment needs. For example, as highlighted by Onslow and Lowe (2019), the Restart DCM treatment describes more than 60 strategies for environmental change that clinicians can select from to develop an individualised treatment for each child. Detailed protocols and descriptions of deviations from protocols is therefore imperative to enable accurate evaluation of available stuttering interventions, particularly given there is significant scope within some of these interventions to individualise the treatment substantially.

Many of the included studies in our review did not report on monitoring home sessions or clinical sessions. Monitoring home and clinical sessions of stuttering interventions is necessary to be able to conclude that the delivered treatment is the same as the intended treatment outlined within a treatment protocol/manual (Onslow & Lowe, 2019; Öst, 2008). Further, treatment outcomes observed within a trial may be a direct reflection of how accurately a treatment was delivered and could eliminate a potential bias within the evaluation of the intervention outcomes. That is, a parent or SLP who adheres to the intended treatment more closely than other parents or SLPs in the same trial may observe better outcomes for their child (Durlak, 2015).

Of those studies which did monitor clinicians and/or parents delivery of intervention, findings indicated that monitoring strategies varied between audio and/or video recordings, logs, live observations and observations using one-way mirrors. In stuttering research, the choice of monitoring strategy may affect the quality of data collected. For example, it is arguably more difficult to confirm accuracy of parent responses to stuttering moments when data is reviewed using audio recordings only as inaudible stuttering behaviours such as blocks may be missed. Video recordings would theoretically provide more information and allow researchers to evaluate delivery of intervention more accurately. Monitoring of treatment delivery, both in the clinic and at home, should therefore be described in greater detail in future clinical trials and wherever possible employ audio-visual recordings to enable accurate analysis of intervention delivery. The lack of data reported in the included studies of this review regarding monitoring of clinic and home sessions may reflect the additional time and financial resources required to monitor participants, parents and clinicians. Use of modern technologies such as smart phone applications may ease aspects of data collection. For example, by programming reminders and subsequently recordings of clinical and home intervention sessions into smart phone applications it may increase a researcher's ability to collect this data.

This review revealed that while parent training is generally well detailed and provided in clinical trials, limited information is often given about the background and training of the clinicians. A parent's successful delivery of stuttering intervention will in part be dependent on the quality of education and training provided to them by their clinician. Providing training to clinicians prior to and during intervention could also limit the variability of intervention implementation quality between participants during clinical trials (Domitrovich et al., 2008). We acknowledge that SLP is not a formally recognised profession in every country and that professionals other than SLPs may contribute to the treatment of children who stutter. However, irrespective of whether the clinician is an SLP, experience with the specific intervention program being evaluated cannot be assumed. Pre-intervention training may also reduce potential clinician bias to some extent as SLPs may have varying levels of experience with different stuttering intervention programs. Based on the findings of this review, it is recommended that details regarding the treating clinician's professional background, level of experience with the evaluated intervention, pre-intervention training and support procedures provided during the intervention are

reported (Hoffmann et al., 2014).

5.2. Use of implementation quality elements within effect calculations and discussion of reported outcomes

Our second research question examined to what extent implementation quality data were used to analyse the intervention outcome and/or discuss the reported outcomes of stuttering interventions in clinical trials. Whilst all the included studies reported on at least one element of implementation quality, it was surprising to note that only one third of these studies considered implementation quality in their outcome analyses. For most of the included studies, the relationship between implementation quality and treatment outcome were neither determined nor discussed. While the reason for this is not known, this low figure might reflect the complex process required to evaluate the influence of various elements of implementation quality on treatment effectiveness (Durlak, 2015).. This assumption is reinforced by our finding that intervention dosage was the only implementation quality element used in analysis and was also the most common implementation quality element included in discussions of findings. Specifically, intervention dosage was used to investigate if the number of clinical hours or sessions to complete Stage 1/reach Stage 2 differed between the treatment group and the active control group. Evaluation of an association between intervention dosage and effectiveness is arguably straightforward to conduct compared to more complex analyses potentially required to examine associations with other implementation quality elements such as quality of clinician or parent training (Domitrovich et al., 2008).

While evaluating the relationship between intervention dosage and intervention outcomes is essential, it is equally as important to evaluate how the intervention is being delivered by parents. Our finding that monitoring strategies and/or adherence to treatment protocols were not considered in effect calculations and parent delivery of treatment was only discussed in a few of the studies included in this review is therefore worthy of mention. Information about a treatment provider's experience and how they delivered intervention throughout a trial (e.g. affective engagement and responsiveness from SLP or parents) in addition to how this aspect of implementation quality was monitored would enable researchers to evaluate compliance with an intervention protocol and thus quality of delivery (Domitrovich et al., 2008). This could be analysed using multilevel methods examining each SLP and the children they treat in a cluster however this would require adequate statistical power. This data seems essential for stuttering intervention research as clinicians and/or parents who do not adhere to the prescribed treatment protocol are more likely to generate poorer intervention outcomes which would ultimately be a misrepresentation of the effectiveness of the intervention. For example, using recordings of parents delivering the Lidcombe Program in their homes, Swift et al. (2016) found that frequency of strategies used during treatment sessions was significantly related to treatment time. This highlights the importance of evaluating intervention dosage, including for example frequency of strategies used during treatment sessions, to get a clearer picture of how an intervention is being delivered. In some instances, collecting this information may also generate observations which lead to further revisions and improvements of a treatment program. Interestingly, meta-analyses in other areas such as anti-bullying programs in school and mentoring programs for youth have found that intervention studies which include monitoring intervention implementation obtain much higher effect sizes than programs without monitoring (Durlak & DuPre, 2008). This further reinforces the notion that monitoring is a worthwhile detail to consider when planning an intervention.

5.3. Implementation quality and time of publication

In the third research question, we evaluated if implementation quality was related to year of publication. This review included studies published between 1974 and 2019. Considering the ever-evolving changes to research methodology which demand stricter requirements for intervention protocols and higher standards for study reporting (see CONSORT statement; (Schulz et al., 2010), we expected newer publications to provide stronger evidence of implementation quality. This hypothesis however was not supported by our findings, the correlation between publication year and implementation quality score was very low (rho = 0.03) and not significant, but the sample was small. While our findings show an increase in published stuttering interventions, we reiterate Nye et al. (2013) comment that the amount of evidence for stuttering interventions is still low overall. One possible reason for this is the unique complexity faced by researchers evaluating stuttering interventions for children as they must account for the phenomenon of natural recovery. Another important acknowledgement to make is the significant undertaking required to detail and evaluate all relevant elements of implementation quality within a clinical trial. Such efforts require adequate staffing and consequently funding to support the collection of detailed information about implementation quality.

5.4. Limitations

Assessing the implementation quality elements reported in studies posed some challenges. While some studies described implementation quality explicitly and provided details in an easily accessible format within the methodology, other studies provided implementation quality elements within the abstract, table notes and/or discussion. Descriptions of some elements such as training and support provided to the treating clinician were often unclear. This may be because these details are provided in the intervention manual referred to within publications or because it is considered assumed knowledge. Alternatively, word count restrictions placed on publications may limit the amount of information that can be provided in each article. Studies included in this review may therefore have collected more detailed information about implementation quality but not made them available in their publications for reasons stated above.

One implementation quality element that may be evaluated differently in stuttering interventions compared to interventions for other disorders is the prescribed intervention dosage. In stuttering interventions, the time spent at different stages of intervention may

be criterion based (e.g., meeting pre-determined thresholds for stuttering severity) as opposed to the time spent at each stage of the intervention process being uniform across participants.

It is also important to acknowledge that improving the quality of data reported for some implementation quality elements may interfere with other elements such as intervention completion and attrition. For example, a detailed monitoring system to assess treatment compliance at home will enhance the reliability of this content but may also increase the demands placed on parents. Consequently, this may increase the attrition rate in studies. The use of technology such as video recordings may present a solution that is less time demanding for parents whilst also providing a rich source of data regarding intervention delivery and dosage adherence in the home setting.

Finally, this study only investigated implementation quality within published papers with QED and RCT designs. There is therefore a need to investigate implementation quality in clinical trials for children who stutter using other designs (e.g., baseline studies).

5.5. Conclusions

The findings of this review revealed that there is a lack of detail about implementation quality elements reported in published clinical trials of stuttering interventions for children and adolescents. The treatment programs in this review were delivered for 4–62 weeks, indicating that a large amount of time and effort was dedicated to intervention by children who stutter, parents and SLPs. While all included studies reported on at least one element of implementation quality, none of the studies reported on all elements of implementation quality to enable more accurate evaluation of reported treatment outcomes. We therefore posit that there is a need for clear guidelines specifically developed for stuttering intervention trials to ensure systematic and thorough collection and reporting of implementation quality elements. This study investigated implementation quality of published papers with RCT and QED designs. There is therefore an outstanding need for the implementation quality of clinical trials of stuttering interventions for children that have adopted other designs (e.g., single subject studies) to be investigated.

Inspired by TIDieR guidelines (Hoffmann et al., 2014) and the CONSORT 2010 Checklist (Schulz et al., 2010), we used the results of this review, to develop a checklist for researchers to use in the design and reporting of future clinical trials of stuttering interventions. The checklist provides a comprehensive list of individual elements of implementation quality that researcher could use when planning and conducting their trials (see Appendix B). It is our hope that application of this checklist in future trials of stuttering interventions will enhance implementation quality and consequently intervention validity, reliability and replicability. Improving implementation quality of future clinical trials of stuttering interventions could equip SLPs with more accurate knowledge about effective interventions so that better informed decisions can be made about management of stuttering in children and adolescents.

Declaration of Competing Interest

We have no conflict of interests to disclose.

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Appendix A. Characteristics of excluded studies

Study	Reason for exclusion
Al-Khaledi, M., Lincoln, M., McCabe, P., & Alshatti, T. (2018) The Lidcombe Program: a series of case studies with Kuwaiti preschool children who stutter. *Speech, Language, and Hearing*, *21*(4), 224−235.	No control group
Bray, M. A. & Kehle, T. J. (1998). Self-modeling as an intervention for stuttering. *School Psychology Review*, *27*(4), 587−598.	No control group
Butcher, C., McFadden, D., Quinn, B., & Ryan, B. P. (2003). The effects of language training on stuttering in young children, without and with contingency management. *Journal of Developmental and Physical Disabilities*, *15*(3), 255−280.	No control group
Caron, C. & Ladouceur, R. (1989). Multidimensional behavioral treatment for child stutterers. *Behavior Modification*, *13*(2), 206−215.	No control group
Druce, T., Debney, S., & Byrt, T. (1997). Evaluation of an intensive treatment program for stuttering in young children. *Journal of Fluency Disorders*, *22*(3), 169−186.	No control group
Hasbrouck, J. M., Doherty, J., Mehlmann, M. A., Nelson, R., Randle, B., & Whitaker, R. (1987). Intensive stuttering therapy in a public school setting. *Language, Speech, and Hearing Services in Schools*, *18*(4), 330−343.	Age, participant over 17 years.
Hearne, A., Packman, A, Onslow, M, & O'Brian, S. (2008). Developing treatment for adolescents who stutter: A phase I trial of the Camperdown Program. *Language, Speech and Hearing Services in Schools*, *39*(4), 487−497.	No control group
Koushik, S., Shenker, R., & Onslow, M. (2009). Follow-up of 6−10-year-old stuttering children after Lidcombe Program treatment: A phase I trial. *Journal of Fluency Disorders*, *34*(4), 279−290.	No control group
Mallard, A. R. (1998). Using problem-solving procedures in family management of stuttering. *Journal of Fluency Disorders*, *23*(2), 127−135.	No control group
Martin, R. R., Kuhl, P., & Haroldson, S. (1972). An experimental treatment with two preschool stuttering children. *Journal of Speech and Hearing Research*, *15*(4), 743−752.	No control group
	No control group

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(*continued*)

Study	Reason for exclusion
Millard, S. K., Edwards, S., & Cook, F. M. (2009). Parent-Child Interaction Therapy: Adding to the evidence, *International Journal of Speech-Language Pathology*, *11*(1), 61−76.	
Onslow, M., Costa, L., & Rue, S. (1990). Direct early intervention with stuttering some preliminary data. *Journal of Speech and Hearing Disorders*, *55*(3), 405−416.	No control group
Rousseau, I., Packman, A., Onslow, M., Harrison, E., & Jones, M. (2007). An investigation of language and phonological development and the responsiveness of preschool age children to the Lidcombe Program. *Journal of Communication Disorders*, *40*(5), 382−397.	No control group
Ryan, B. P., & van Kirk Ryan, B. (1983). Programmed Stuttering Therapy for Children: Comparison of Four Establishment Programs. *Journal of Fluency Disorders*, *8*(4), 291−321.	Age, participant over 17 years
Shafiei, B., Faramarzi, S., Abedi, A., Dehqan, A., & Scherer, R. C. (2019). Effects of the Lidcombe Program and Parent-Child Interaction Therapy on stuttering reduction in preschool children. *Folia Phoniatrica et Logopaedica*, *71*(1), 29−41.	No control group
Trajkovski, N., Andrews, C. R., Onslow, M., Packman, A., O'Brian, S., & Menzies, R. G. (2009). Using syllable-timed speech to treat preschool children who stutter: a multiple baseline experiment. *Journal of Fluency Disorders*, *34*(1), 1−10.	No control group
Yaruss, J. S., Coleman, C., & Hammer, D. (2006). Treating preschool children who stutter: description and preliminary evaluation of a family-focused treatment approach. *Language, Speech and Hearing Services in the Schools*, *37*(2), 118−136.	No control group
Vong, E., Wilson, L., & Lincoln., M. (2016). The Lidcombe Program of early stuttering intervention for Malaysian families: Four case studies. *Journal of Fluency Disorders*, *49*, 29−39.	No control group
Wagaman, J. R., Miltenberger, R. G., & Arndorfer, R. E. (1993). Analysis of a simplified treatment for stuttering in children. *Journal of Applied Behavior Analysis*, *26*(1), 53–61.	No control group
Wilson, L.H., Onslow, M., & Lincoln, M. (2004). Telehealth adaptation of the Lidcombe Program of early stuttering intervention: five case studies. American Journal of Speech-language Pathology, 13(1), 81−93.	No control group

Appendix B. A checklist for reporting clinical trials of non-pharmacological stuttering interventions

Topic	Checklist item	Reported on page no
Protocol	Description of intervention protocol, detailed enough to enable replication	
	Where the intervention protocol can be accessed (if available)	
Delivery systems	Setting and location where clinic visits are conducted (inc service delivery mode)	
Clinic visits	Person(s) responsible for delivering intervention	
Treatment sessions	Setting and location where treatment sessions are conducted (inc service delivery mode)	
	Person(s) responsible for delivering intervention	
Support and training	Treating clinician's professional background and level of experience with evaluated intervention	
Pre-intervention	Training and/or other support provided to clinician	
	Training and/or other support provided to parent/carer	
During intervention	Training and/or other support provided to clinician	
	Training and/or other support provided to parent/carer	
Intervention dosage (planned)		
Clinic visits	Prescribed length of each clinical visit	
	Prescribed frequency of clinical visits	
	Prescribed number of clinical visits required and/or criteria for completing each stage/phase of intervention	
Home treatment sessions	Prescribed length of each treatment session at home	
	Prescribed frequency of treatment sessions at home	
	Prescribed number of treatment sessions required at home and/or criteria for completing each stage/phase of intervention	
Intervention dosage (delivered)		
Clinic visits	Delivered length of each clinical visit	
	Delivered frequency of clinical visits	
	Delivered number of clinical visits required and/or criteria for completing each stage/phase of intervention	
Home treatment sessions	Delivered length of each treatment session at home	
	Delivered frequency of treatment sessions at home	
	Delivered number of treatment sessions required at home and/or criteria for completing each stage/phase of intervention	
Maintenance dosage (planned)		
Clinic visits	Prescribed length of each clinical visit	
	Prescribed frequency of clinical visits	
	Prescribed number of clinical visits required and/or criteria for completing each stage/phase of intervention	
Home treatment sessions	Prescribed length of each treatment session at home	
	Prescribed frequency of treatment sessions at home	
	Prescribed number of treatment sessions required at home and/or criteria for completing each stage/phase of intervention	
Maintenance dosage (delivered)		
Clinic visits	Delivered length of each clinical visit	

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(*continued*)

Topic	Checklist item	Reported on page no
	Delivered frequency of clinical visits	
	Delivered number of clinical visits required and/or criteria for completing each stage/phase of intervention	
Home treatment sessions	Delivered length of each treatment session at home	
	Delivered frequency of treatment sessions at home	
	Delivered number of treatment sessions required at home and/or criteria for completing each stage/phase of intervention	
Treatment adaptations		
Content	Changes to intervention content implemented for some/all participants after trial commenced and not otherwise stated in protocol, with reasons	
Dosage	Changes to intervention dosage implemented for some/all participants after trial commenced and not otherwise stated in protocol, with reasons	
Monitoring treatment fidelity		
Clinic visits	Audio-visual recording of clinical visits	
Treatment sessions	Audio-visual recording of treatment sessions at home	

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Hilde Hofslundsengen is an associated professor at the Western Norway University of Applied Sciences, Norway. Her research interests include the intervention methodology and stuttering treatment.

Melanie Kirmess is an associated professor within speech and language pathology at the University of Oslo and a researcher at Sunnaas Rehabilitation Hospital, Norway. Her research includes acquired language disorders and intervention methodology and outcome.

Linn Stokke Guttormsen holds a postdoc position in stuttering research, University of Oslo, Norway. Her research interests include stuttering in young children, in particular how children are affected by stuttering and stuttering treatment.

Kari-Anne Bottegaard Næss is a Professor in Speech and language pathology at the Department of Special Needs Education, University of Oslo, Norway. She has practical experience as teacher, special needs education teacher and SLP. Her research interests includes mainly communication and language development in children with typical and atypical development as well as related interventions. Næss is leading is the The Effective Stuttering Treatment (EST) project.

Elaina Kefalianos is the Lead of Teaching and Senior Lecturer for Speech Pathology at the University of Melbourne, Australia. She is the Vice-President for the Stuttering Association for the Young: Australia. She has more than a decade of clinical experience treating children who stutter. Her research focuses exclusively on stuttering with a particular interest in epidemiology and intervention.