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The Quality of Reporting of Pilot and Feasibility Cluster Randomised Trials: A Systematic Review

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ABSTRACT

Background: There are an increasing number of studies described as pilot and feasibility studies. Reporting is generally poor. These studies are particularly important when designing cluster randomised trials (CRTs).

Objectives: To systematically review the quality of reporting of pilot and feasibility CRTs. In particular, to assess (1) the number of pilot CRTs conducted between 01/01/2011 and 31/12/2014, (2) whether objectives and methods are appropriate and (3) reporting quality.

Methods: We searched PubMed (2011-2014) for CRTs with 'pilot' or 'feasibility' in the title or abstract; that were assessing some element of feasibility; and showing evidence the study was in preparation for a main effectiveness/efficacy trial. Quality assessment criteria were based on the Consolidated Standards of Reporting Trials (CONSORT) extensions for pilot trials and CRTs.

Results: Eighteen pilot CRTs were identified. Forty-four percent did not have feasibility as their primary objective, and many (50%) performed formal hypothesis testing for effectiveness/efficacy despite being underpowered. Most (83%) included 'pilot' or 'feasibility' in the title, and discussed implications for progression from the pilot to the future definitive trial (89%), but fewer reported reasons for the randomised pilot trial (39%), sample size rationale (44%), or progression criteria (17%). Most defined the cluster (100%), and number of clusters randomised (94%), but few reported

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how the cluster design affected sample size (17%), whether consent was sought from clusters (11%), or who enrolled clusters (17%).

Conclusions: That only 18 pilot CRTs were identified necessitates increased awareness of the importance of conducting and publishing pilot CRTs and improved reporting. Pilot CRTs should primarily be assessing feasibility, avoiding formal hypothesis testing for effectiveness/efficacy, and reporting reasons for the pilot, sample size rationale, and progression criteria, as well as enrolment of clusters, and how the cluster design affects design aspects. We recommend adherence to the CONSORT extensions for pilot trials and CRTs.

Article summary

Strengths and limitations of this study

- We used a robust search and data extraction procedure, including validation of the screening/sifting process and double data extraction.
- We may have missed some studies, since our criteria excluded studies not including 'pilot' or 'feasibility' in the title or abstract, and those not clearly in preparation for a main trial.

BACKGROUND

In a cluster randomised trial (CRT) clusters, rather than individuals, are the units of randomisation. A cluster is a group (usually predefined) of one or more individuals. For example, clusters could be hospitals and the individuals, the patients within those hospitals. CRTs are often chosen for logistical reasons, prevention of contamination across individuals, or because the intervention is targeted at the cluster level. CRTs are useful for evaluating complex interventions. However, they have added complexity in terms of design, implementation, and analysis and so it is important to ensure that carrying out a CRT is feasible before conducting the future definitive trial.[1]

A feasibility study conducted in advance of a future definitive trial is a study designed to answer the question about whether the study can be done and whether one should proceed with it. A pilot study answers the same question but in such a study part or all of the future trial is carried out on a smaller scale.[2] Thus all pilot studies are also feasibility studies. Pilot studies can be randomised or

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non-randomised; for brevity we use the term pilot CRT throughout this paper to refer to a randomised study with a clustered design that is in preparation for a future definitive trial assessing effectiveness/efficacy.[3, 4] The focus of pilot trials is on investigating areas of uncertainty about the future definitive trial to see whether it is feasible to carry out, so the data, methods, and analysis are different from an effectiveness/efficacy trial. In particular, more data might be collected on items such as recruitment and retention to assess feasibility, methods may include specifying criteria to judge whether to proceed with the future definitive trial, and analysis is likely to be based on descriptive statistics since the study is not powered for formal hypothesis testing for effectiveness/efficacy.

Arnold et al. highlight the importance of pilot studies being of high quality.[5] Good reporting quality is essential to show how the pilot has informed the future definitive trial as well as to allow readers to use the results in preparing for similar future trials. The number of pilot and feasibility studies in the literature is increasing. However, Arain et al. indicate that reporting of pilot studies is poor.[6] There are no previous reviews of the reporting quality of pilot CRTs, despite the extra complications arising from the clustered structure. The aim of this review is to reveal the quality of reporting of pilot CRTs published between 01/01/2011 and 31/12/2014. We extracted information to describe the sample of pilot CRTS and to assess quality, with quality criteria based on the Consolidated Standards of Reporting Trials (CONSORT) extension for CRTs,[7] and a CONSORT extension for pilot trials which SE and CC were involved in the final stages of development of during this review.[3, 4] We present recommendations for improving the conduct, analysis and reporting of these studies and expect this to improve the quality, usefulness and interpretation of pilot CRTs in the future. We know current reporting of CRTs is suboptimal,[8-11] and thus we expected the reporting of pilot CRTs to be even poorer.

The questions addressed by this review are:

1) How many pilot CRTs have been conducted between 01/01/2011 and 31/12/2014?
2) Are pilot CRTs using appropriate objectives and methods?
3) To what extent is the quality of reporting of pilot CRTs sufficient?

METHODS

Inclusion and exclusion criteria

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We included papers published in English with a publication date (print or electronic) between 01/01/2011 and 31/12/2014. These dates were chosen to ensure we identified recent papers, with the start date being after the updated CONSORT 2010 was published.[12] The study had to be a CRT, have the word 'pilot' or 'feasibility' in the title or abstract, be assessing some element of feasibility, and show evidence that the study was in preparation for a trial assessing effectiveness/efficacy. Regardless of how authors described a study, we did not consider it to be a pilot trial if it was *only* looking at effectiveness/efficacy because we wanted to exclude those studies that claim to be a pilot/feasibility trial simply as justification for small sample size.[13] The paper had to be reporting results (i.e. not a protocol or statistical analysis plan) and had to be the first published paper reporting pilot outcomes (i.e. not an extension/follow-up study for a pilot study already reported, and not a second paper reporting further pilot outcomes). Interim analyses, analyses before the study was complete, and internal pilots were excluded; the CONSORT extension for pilot trials on which we based the quality assessment does not apply to internal pilots.[3, 4] No studies were excluded on the basis of quality since the aim was to assess the quality of reporting.

Data sources and search methods

We searched PubMed for relevant papers in September 2015. We searched for the words 'pilot' or 'feasibility' in the title or abstract, a search strategy similar to that used by Lancaster et al. [14] We combined this with a search strategy to identify CRTs; this was similar to the strategy used by Diaz-Ordaz et al. [8] The full electronic search strategy is given in Appendix 1.

Sifting and validation

The titles and abstracts of all papers identified by the electronic search were screened by CC for possible inclusion. Full texts were obtained for those papers identified as definitely or possibly satisfying the inclusion criteria and sifted by CC for inclusion. As validation, CL carried out the same screening and sifting process independently on a 10% random sample of electronically identified papers. For full texts where there was uncertainty whether the paper should be included, it was referred to SE for a final decision.

Refining the inclusion process

We refined the screening and sifting process following piloting. In particular we rejected a more restrictive PubMed search that required 'pilot' or 'feasibility' in the title rather than allowing these words to occur in the title *or* abstract because this missed relevant papers; we altered the order of the exclusion criteria to make the process more streamline; and we relaxed one inclusion criteria,

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requiring evidence that the pilot trial was in preparation for a future definitive trial rather than an explicit statement that authors were planning a future definitive trial. The protocol was updated, and is available from the corresponding author.

Data Extraction

CC and CL independently extracted data from all papers selected for inclusion in the review. Written guidance was used, and extracted data were recorded in an Excel spreadsheet. Discrepancies were resolved by discussion between CC and CL, and where agreement could not be reached a final decision was made by SE.

For each pilot CRT included in the review, we extracted information to describe the trials, including publication date (print date unless there was an earlier electronic date), country in which the trial was set, number of clusters randomised, method of cluster randomisation and, following the CONSORT extension for pilot trials' recommendation to focus on objectives rather than outcomes, the primary objective. We defined the primary objective using method similar to that used by Diaz-Ordaz *et al*.[8] for primary outcomes i.e. as that specified by the author, else the objective used in the sample size justification, or else the first objective mentioned in the abstract or else main text.

To assess whether the pilot trials were using appropriate objectives and methods, we collected information on whether the primary objective was about feasibility, the method used to address the main feasibility objective, the rationale for numbers in the pilot trial, and whether there was formal hypothesis testing for, or statements about, effectiveness/efficacy without a caveat about the small sample size.

To assess reporting quality, we created a list of items based on the CONSORT extension for pilot trials,[3, 4] and the CONSORT extension for CRTs.[7] We recognised the need to balance comprehensiveness and feasibility.[11] Therefore, where there was no real change between the CONSORT 2010 for randomised controlled trials (RCTs),[12] and either of the CONSORT extensions,[3, 4, 7] and we expected the item would be generally well-reported, the item was not extracted (e.g. structured summary of trial design, methods, results, and conclusions). Moreover, where items referred to objectives or methods, we extracted this for the primary objective only. Where a CRT item became less relevant in the context of a pilot trial, we did not extract it (e.g. whether variation in cluster sizes was formally considered in the sample size calculation). In addition, where there was a substantial difference between the item for either the CONSORT 2010 for RCTs or

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the CRT extension and that for the pilot trial extension and the items were not compatible, we used the latter item (e.g. focusing on objectives rather than outcomes). The final version of the full list of data extracted, and further information on each item extracted, is included in Appendix 2.

Refining data extraction

Initially CC extracted data on a random 10% sample of papers. However, some of the items, in particular some of the CRT-specific items such as whether the intervention or allocation concealment were at the individual level, cluster level, or both, were difficult to extract in a clear, standardised way, as similarly noted by Ivers et al,[11] so these items were removed. Furthermore, some items were deemed easier to extract if split into two items, for example; 'reported why the pilot trial ended/stopped' which we subsequently split into 'reported the pilot trial ended/stopped' and 'if so, what was the reason'.

Analysis

Data were analysed using Excel version 2013. We describe the characteristics of the pilot CRTs using descriptive statistics. Where we extracted text, we established categories during analysis by grouping similar data, for example grouping the different primary objectives. To assess adherence to the CONSORT checklists, we present the number and percentage reporting each item. This report adheres, where appropriate, to the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) statement.[15]

Patient involvement

No patients were involved in the development of the research question, design or conduct of the study, interpretation or reporting. No patients were recruited for this study. There are no plans to disseminate results of the research to study participants.

RESULTS

The electronic PubMed search identified 257 published papers. We rejected 108 during screening (29 not reporting results; 32 not about a single randomised trial; 46 not cluster randomised; 1 interim analysis). The remaining 149 full-text articles were assessed for eligibility, and 131 more papers were rejected (1 not reporting results; 13 not about a single randomised trial; 25 not cluster

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randomised; 8 analyses before study complete/internal pilot; 32 not assessing feasibility; 50 not in preparation for a future definitive effectiveness/efficacy trial; 2 not the first published paper reporting pilot outcomes). This left 18 studies to be included in the analysis.[A1-A18]. The full list of studies is included in Appendix 3. Figure 1 shows the flow diagram of the identification process for the sample of 18 pilot CRTs.

There was 96% agreement between CC and CL for the 10% random sample used for the screening and sifting validation (based on 26 papers), with a kappa coefficient of 0.84.

Trial characteristics

In general, the more recent the publication date, the more pilot CRTs were identified, but with the most identified in 2013 (Table 2). Of the 18 included studies, the majority (56%) were set in the UK. All other countries were represented only once except for Canada (3 trials) and USA (2 trials). Of those reporting the method of randomisation, the majority (69%) used stratified with blocked randomisation. The median number of clusters randomised was 8 (IQR: 4 to 16) with a range from 2 to 50.

Pilot trial objectives and methods

Ten (56%) of the 18 included pilot trials had feasibility as their primary objective, for example assessing feasibility of implementing the intervention (6 trials), of recruitment and retention (3 trials), and of the cluster design (1 trial) (Table 3). All ten trials reported a corresponding measure to assess the feasibility objective; most (90%) used descriptive statistics and/or qualitative methods to address the objective. In one trial a statistical test was used to address their primary feasibility objective without the authors designing the study to be adequately powered to do so.

The remaining eight trials had an effectiveness/efficacy primary objective, and used statistical tests to address this. Nevertheless these eight trials all had feasibility as one of their other objectives (this was an inclusion criterion). The feasibility objectives were similar to those where the feasibility was primary, but expressed more generally in two trials, for example, looking at the feasibility of the future definitive trial,[A16] and looking at whether the future definitive trial could answer the effectiveness question and which study design would enable this.[A10] In only three trials was a measure to assess the feasibility objective reported, using either quantitative or qualitative measures.

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All eight trials that reported a rationale for the numbers in the pilot trial followed best practice in not basing this rationale on a formal sample size calculation for effectiveness/efficacy. In the nine (50%) trials where formal hypothesis testing was reported (the one trial using a statistical test for the feasibility primary objective and the eight trials using statistical tests for the non-feasibility primary objectives), four of the conclusions about effectiveness/efficacy were made without any caveats about the imprecision of estimates or possible lack of representativeness because of the small samples.

Quality of reporting

To present data on quality of reporting we grouped reporting items into three categories (Table 4): (1) new items added to the CONSORT extension for pilot trials, (2) items in the CONSORT extension for pilot trials that were substantially adapted from CONSORT 2010 for RCTs and (3) items in the CONSORT extension for pilot trials that were the same as or with only minor differences from CONSORT 2010 for RCTs plus items in the CONSORT extension for CRTs.[3, 4, 7, 12]

New items

Five new items were added to the CONSORT extension for pilot trials on the identification and consent process, progression criteria, other unintended consequences, implications for progression, and ethical approval.[3, 4] In our review, how participants were identified and consented was reported by 50% and 76% of the pilot CRTs, respectively, but how clusters were identified and consented was reported by just 33% and 11%, respectively. Only 3 trials (17%) reported criteria used to judge whether or how to proceed with the future definitive trial, with two giving numbers that must be exceeded such as recruitment, retention, attendance, and data collection percentages,[A17, A2] and one giving categories of “definitely feasible”, “possibly feasible”, and “not feasible”.[A12] The item on other unintended consequences was reported by none of the pilot CRTs, although it is unclear whether this is due to poor reporting or because no unintended consequences occurred. Implications for progression from pilot to future definitive trial was reported by 16 trials (89%), with nine reporting to proceed/proceed with changes, five reporting further research or piloting is needed first, and two reporting to not go ahead with the future definitive trial. 94% reported ethical approval/research review committee approval, but only 47% of them also reported the corresponding reference number.

Substantially adapted items

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Six items in the CONSORT extension for pilot trials were substantially adapted from CONSORT 2010 for RCTs, regarding reasons for the randomised pilot trial, sample size rationale, numbers approached and/or assessed for eligibility, remaining uncertainty about feasibility, generalisability of pilot trial methods and findings, and where the pilot trial protocol can be accessed.[3, 4] Reasons for the randomised pilot trial were reported by 39% of the pilot CRTs. Eight trials (44%) gave a rationale for the sample size of the pilot trial, based on logistics,[A15] resources,[A14] time,[A16] a balance of practicalities and need for reasonable precision,[A18] a general statement that it was considered sufficient to address the objectives of the pilot trial,[A17] formal [A6] and non-formal [A7] calculation to enable estimation of parameters in the future definitive trial, and a formal calculation based on the primary feasibility outcome.[A12] The number of individuals approached and/or assessed for eligibility was reported by 47%, and the number of clusters by 56%. Remaining uncertainty was reported by 56% of the pilot CRTs. 89% reported generalisability of pilot trial methods/findings to the future definitive trial or other studies, but clarity of reporting was lacking as it was difficult to distinguish between references to the future definitive trial versus other future studies due to ambiguous phrases such as “in a future trial”. Only 39% reported where the pilot trial protocol could be accessed.

Items essentially taken from CONSORT 2010 for RCTs or the CONSORT extension for CRTs

For the remaining items, reporting quality was variable. Some were reported by fewer than 20% of the pilot CRTs, for example considering the cluster design in the sample size rationale (17%), reporting whether consent was sought from clusters (11%) and who enrolled them (17%), how people were blinded (7% of applicable trials), number of excluded individuals (6% of applicable trials) and clusters (18% of applicable trials) after randomisation, and a table showing baseline cluster characteristics (11%). Those reported most well, by more than 80% of the pilot CRTs, included reporting ‘pilot’ or ‘feasibility’ in the title (83%), scientific background and explanation of rationale for future definitive trial (100%), pilot trial design (100%), nature of the cluster (100%), settings and locations where the data were collected (100%), whether consent was sought from participants (94%), number of clusters randomised (94%) and assessed for primary objective (82% of applicable trials), number of individuals assessed for primary objective (94% of applicable trials), limitations of pilot trial (94%), and source of funding (100%).

DISCUSSION

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Main findings

This is the first study to assess the reporting quality of pilot CRTs using the recently developed CONSORT checklist for pilot trials.[3, 4] Our search strategy and inclusion criteria identified 18 pilot CRTs published between 2011 and 2014. Most studies were published in the UK, perhaps driven by the availability of funding or the large number of CRTs and interest in complex interventions in the UK.

With respect to the pilot CRT objectives and methods, a considerable proportion of papers did not have feasibility as their primary objective. Of the trials reporting a sample size rationale, all followed best practice in not carrying out a formal sample size calculation for effectiveness/efficacy, yet a substantial proportion performed formal hypothesis testing for effectiveness/efficacy. This could indicate an inappropriate attachment to hypothesis testing, although many did explain it was an indication of *potential* effectiveness or that the study was underpowered. Investigators wanting to assess effectiveness/efficacy and use statistical tests to do so should be performing a properly powered definitive trial, otherwise there is the potential for misleading conclusions affecting clinical decisions as well as misinformed decisions about the future definitive trial.[16]

Reporting quality of pilot CRTs was variable. Items reported well included reporting the term 'pilot' or 'feasibility' in the title, generalisability of pilot trial methods/findings to the future definitive trial or other studies, and implications for progression from the pilot to the future definitive trial, although clarity could be improved when referring to the future definitive trial rather than other future studies in general. Items least well reported included reasons for the randomised pilot trial, sample size rationale, criteria used to judge whether or how to proceed with the future definitive trial, and where the pilot trial protocol can be accessed. These items are important so that readers can understand whether the uncertainty they are facing about their future trial has already been addressed in a pilot, researchers can make sure they have enough patients to achieve the pilot trial objectives, readers can understand the criteria for progression, and to prevent against selective reporting.

For items related to the cluster aspect of pilot CRTs, most pilot CRTs reported the nature of the cluster, and the number of clusters randomised and assessed for the primary objective. The items reported least well included considering the cluster design during the sample size rationale, reporting who enrolled clusters and how they were consented, number of exclusions for clusters

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after randomisation, and a table showing baseline cluster characteristics. Moreover, while nearly all trial reports described whether consent was sought from individuals or not, seeking agreement from clusters was only described in a small minority. The items on agreement from and enrolment of clusters, baseline cluster characteristics, and number of excluded clusters are particularly important to report, since they may affect assessment of feasibility.

If we consider why some items may have been well adhered to and others not, it is interesting to observe that new items added to the CONSORT extension for pilot trials and items substantially adapted from CONSORT 2010 for RCTs were in general not well adhered to. This could perhaps be because of somewhat newer ideas that may not have been considered during design such as specifying progression criteria and considering a rationale for numbers in the pilot. Alternatively, perhaps there were aspects sometimes done but not reported due to lack of reporting guidance to remind authors; for example, the new items on how clusters were identified and consented, other unintended consequences, and ethical approval/research review committee approval reference number, and the substantially adapted items on reporting reasons for the pilot trial, number of individuals approached and/or assessed for eligibility, and where the pilot trial protocol can be accessed. It is also interesting to observe that many of the most poorly reported items concerned methods/design (progression criteria; enrolment and consent of clusters), and in particular, justification of design aspects (reasons for randomised pilot trial; sample size rationale including consideration of cluster design).

Comparison with other studies

There has not been a previous review of pilot trials using the new CONSORT extension for these trials.[3, 4] However, the review by Arain et al. looking at pilot and feasibility studies reported that 81% were performing hypothesis testing with sample sizes known to be insufficient,[6] compared to 50% of pilot CRTs in our review. Arain et al. also reported 36% of studies performing sample size calculations. In our review, 17% performed calculations (all based on feasibility objectives), but if we include those that also correctly reported a rationale for the numbers in the pilot but without any calculation then this was 44%.

The general message that reporting of CRTs is suboptimal still holds.[8-11] The review by Diaz-Ordaz et al. (2013) of definitive trial CRTs reported that 37% presented a table showing baseline cluster characteristics, compared to 11% of pilot CRTs in our review. Diaz-Ordaz et al. (2013) also reported that 27% accounted for clustering in sample size calculations,[8] and a recent review by Fiero et al.

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reported 53%.[10] However, just 17% of pilot CRTs in our review considered the cluster design in the sample size rationale. Both these CRT reviews reviewed effectiveness/efficacy CRTs, for which the need to take account of clustering in sample sizes is generally well understood compared to pilot trials. In pilot trials the rationale for considering the clustered design in deciding on numbers in the pilot may be different, for example including a number of clusters with different characteristics to get an idea about the implementation of an intervention across different clusters.

Strengths and limitations

We used a robust search and data extraction procedure, including validation of the screening/sifting process and double data extraction. However, our inclusion criteria stipulated that papers must have the word 'pilot' or 'feasibility' in the title or abstract, so we may have missed some pilot CRTs and thus may have overestimated the percentage reporting 'pilot' or 'feasibility' in the title. Furthermore, we required authors to report that the trial was in preparation for a future definitive trial, so we expect that items related to the future definitive trial (e.g. progression criteria, generalisability, implications) may be better reported than they would for all publications of pilot CRTs which might include papers that did not report that they were in preparation for a future definitive trial clearly enough to be included. During sifting, we identified 50 trials that were assessing feasibility but did not show evidence of being in preparation for a future definitive trial. Most were assessing the feasibility of implementing an intervention targeted at members of the public, or discussing feasibility of the intervention with the aim of providing information to help researchers wanting to implement a similar intervention in similar settings or to raise questions for future research, rather than being in preparation for a trial assessing effectiveness/efficacy. Some of these 50 trials also appeared to be small effectiveness studies labelled as a pilot, usually only mentioning feasibility once or twice throughout the paper, with one trial explicitly stating that "Because of organizational changes… we had to stop the inclusion after 46 participants, and the study is consequently defined as a pilot study."[17] For the few trials that were potentially pilot CRTs not reported clearly enough, authors only spoke of future studies in general rather than clearly specifying the study was in preparation for a specific future definitive trial. Related to this, it is of interest to know the proportion of our 18 pilot CRTs that are actually followed by a future definitive trial, and we plan to investigate this in future.

CONCLUSION

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We may have overestimated the reporting quality of pilot CRTs; nevertheless our review demonstrates that reporting of pilot CRTs need improving. The identification of just 18 pilot CRTs between 2011 and 2014, mainly from the UK, highlights the need for increased awareness of the importance of carrying out and publishing pilot CRTs and good reporting so that these studies can be identified. Pilot CRTs should primarily be assessing feasibility, and avoiding formal hypothesis testing for effectiveness/efficacy. Improvement is needed in reporting reasons for the pilot, rationale for the sample size, and progression criteria, as well as the enrolment stage of clusters and how the cluster design affects aspects of design such as numbers of participants. We recommend adherence to the new CONSORT extension for pilot trials, in conjunction with the CONSORT extension for CRTs.[3, 4, 7] We encourage journals to endorse the CONSORT statement, including extensions.

CONTRIBUTORS:

SE conceived the study and advised on the design and protocol. CC developed the design of the study, wrote the protocol, and designed the screening/sifting and data extraction sheet. CC performed screening and sifting on all papers identified by the electronic search, and CL carried out validation of the screening/sifting process. CC and CL performed independent data extraction on all papers included in the review. CC conducted the analyses of the data and took primary responsibility for writing the manuscript. All authors provided feedback on all versions of the paper. All authors read and approved the final manuscript. CC is the study guarantor.

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This manuscript is an honest, accurate, and transparent account of the study being reported. No important aspects of the study have been omitted, and any discrepancies from the study as planned have been explained.

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TABLES

Table 1: Pilot CRTs included in this review

Author	Year*	Journal	Title	Cluster
Begh [A1]	2011	Trials	Promoting smoking cessation in Pakistani and Bangladeshi men in the UK: pilot cluster randomised controlled trial of trained community outreach workers	Census lower layer super output areas
Jones [A2]	2011	Pediatric Exercise Science	Promoting fundamental movement skill development and physical activity in early childhood settings: a cluster randomized controlled trial.	Childcare centers
Légaré [A3]	2010	Health Expectations	Training family physicians in shared decision making for the use of antibiotics for acute respiratory infections: a pilot clustered randomized controlled trial.	Family medicine groups
Hopkins [A4]	2012	Health Education Research	Implementing organizational physical activity and healthy eating strategies on paid time: process evaluation of the UCLA WORKING pilot study	Worksites - health and human service organizations
Jago [A5]	2012	International Journal of Behavioral Nutrition and Physical Activity	Bristol girls dance project feasibility trial: outcome and process evaluation results	Secondary schools
Taylor [A6]	2011	Clinical Rehabilitation	A pilot cluster randomized controlled trial of structured goal-setting following stroke	Rehabilitation services
Drahota [A7]	2013	Age and Ageing	Pilot cluster randomised controlled trial of flooring to reduce injuries from falls in wards for older people.	Study areas - bays within hospitals
Frenn [A8]	2013	Journal for Specialists in Pediatric Nursing	Authoritative feeding behaviors to reduce child BMI through online interventions	Classrooms
Gifford [A9]	2012	World Views on Evidence-Based Nursing	Developing leadership capacity for guideline use: a pilot cluster randomized control trial.	Service delivery centers with nursing care for diabetic foot ulcers
Jones [A10]	2013	Journal of Medical Internet Research	Recruitment to online therapies for depression: pilot cluster randomized controlled trial.	Postcode areas
Moore [A11]	2013	Substance Abuse Treatment, Prevention, and Policy	An exploratory cluster randomised trial of a university halls of residence based social norms marketing campaign to reduce alcohol consumption among 1st year students.	Residence halls
Pai [A12]	2013	Implementation Science	Strategies to enhance venous thromboprophylaxis in hospitalized medical patients (SENTRY): a pilot cluster randomized trial	Hospitals
Reeves [A13]	2013	BMC Health Services Research	Facilitated patient experience feedback can improve nursing care: a pilot study for a phase III cluster randomised controlled trial.	Wards
Teut [A14]	2013	Clinical Interventions in Aging	Effects and feasibility of an Integrative Medicine program for geriatric patients-a cluster-randomized pilot study.	Shared apartments
Jago [A15]	2014	International Journal of Behavioral Nutrition and Physical Activity	Randomised feasibility trial of a teaching assistant led extracurricular physical activity intervention for 9 to 11 year olds: Action 3:30	Primary schools
Michie [A16]	2014	Contraception	Pharmacy-based interventions for initiating effective contraception following the use of emergency contraception: a pilot study	Pharmacies
Mytton [A17]	2014	Health Technology Assessment	The feasibility of using a parenting programme for the prevention of unintentional home injuries in the under-fives: a cluster randomised controlled trial.	Children's centres
Thomas [A18]	2014	Trials	Identifying continence options after stroke (ICONS): a cluster randomised controlled feasibility trial	Stroke services

* We extracted the earlier of the print and electronic publication year.

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Table 2: Characteristics of pilot CRTs included in this review

Characteristic	Number of trials (%)
Publication year (earlier of the print and electronic publication date)	
2010[a]	1 (6)
2011	3 (17)
2012	3 (17)
2013	7 (39)
2014	4 (22)
Country	
UK	10 (56)
Canada	3 (17)
USA	2 (11)
Germany	1 (6)
New Zealand	1 (6)
Australia	1 (6)
Method of cluster randomisation[b]	
Simple	1 (8)
Stratified with blocks	9 (69)
Blocked only	2 (15)
Bias coin method	1 (8)
Number of clusters randomised[c]	
Median (IQR)	8 (4 to 16)
Range	2 to 50
Average cluster size[d]	
Median (IQR)	32 (14 to 82)
Range	7 to 588

[a] 1 paper has an extracted publication year outside of the 2011 to 2014 range. This is because the print publication date for this paper was 2011 but the online publication date was 2010, so the paper satisfies the inclusion criteria which states that the publication date, print **or** electronic, must be between 2011 and 2014, but we extract the earlier of the print and electronic dates.

[b] 13 of the 18 trials reported their method of randomisation. Percentages are given as a percentage of these 13 trials.

[c] Not reported for 1 trial.

[d] Defined as number of individuals randomised divided by number of clusters randomised, based on 12 trials that reported information on both.

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Table 3: Pilot trial objectives and methods

Characteristic	Number of trials (%)
Primary objective is feasibility [1]	10 (56)
Main feasibility objective given	
Where feasibility is primary objective	
Implementing intervention	6/10 (60)
Recruitment and retention	3/10 (30)
Feasibility of cluster design	1/10 (10)
Where feasibility is not primary objective [2]	
Implementing intervention	3/8 (38)
Recruitment	2/8 (25)
Cluster design	1/8 (13)
Feasibility of trial being able to answer the effectiveness question (and what study design would enable this)	1/8 (13)
Feasibility of larger study	1/8 (13)
Method used to address main feasibility objective given	
Where feasibility is primary objective	
Descriptive statistics and/or qualitative	9/10 (90)
Statistical test	1/10 (10)
Where feasibility is not primary objective	
Descriptive statistics/Qualitative	3/8 (38)
None given/reported elsewhere	5/8 (63)
Rationale for numbers in pilot trial based on formal power calculation for effectiveness/ efficacy [3]	0/8 (0)
Performing any formal hypothesis testing for effectiveness/ efficacy	9/18 (50)
Making any statements about effectiveness/ efficacy without a caveat	4/18 (22)

[1] Where the primary objective was not feasibility, the primary objective was effectiveness/ potential effectiveness and was addressed using statistical tests.
[2] One of the inclusion criteria was that studies were assessing feasibility, but it did not have to be the primary objective
[3] Based on 8 trials that reported a rationale for the sample size of the pilot trial

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Table 4: Number (%) of reports adhering to pilot CRT quality criteria

	Item	Criterion	n(%)
Title and Abstract	1a	Term 'pilot' or 'feasibility' included in the title Identification as a pilot or feasibility randomised trial in the title	15 (83) 12 (67)
	1a	***Term 'cluster' included in the title*** ***Identification as a cluster randomised trial in the title***	12 (67) 12 (67)
Introduction	2a [S]	Scientific background and explanation of rationale for future definitive trial reported Reasons for randomised pilot trial reported	18 (100) 7 (39)
	2a	***Rationale given for using cluster design***	6 (33)
Methods – Trial design	3a	Description of pilot trial design	18 (100)
	3a	***Definition of cluster***	18 (100)
	3b	Reported any changes to methods after pilot trial commencement If yes, reported reasons	5 (28) 5 (100)
Methods – Participants	4a	Reported eligibility criteria for participants	13 (72)
	4a	***Reported eligibility criteria for clusters***	9 (50)
	4b	Reported settings and locations where the data were collected	18 (100)
	4c [N]	Reported how participants were identified ***Reported how clusters were identified*** Reported how participants were consented [1] ***Reported how clusters were consented***	9 (50) 6 (33) 13/17 (76) 2 (11)
Methods – Interventions	5	Described the interventions for each group	13 (72)
Methods - Outcomes	6b	Reported any changes to pilot trial assessments or measurements after pilot trial commencement If yes, reported reasons	1 (6) 1(100)
	6c [N]	Reported criteria used to judge whether, or how, to proceed with the future definitive trial	3 (17)
Methods – Sample size	7a [S]	Reported a rationale for the sample size of the pilot trial	8 (44)
	7a	***Cluster design considered during the description of the rationale for numbers in the pilot trial***	3 (17)
	7b	Reported stopping guidelines	0 (0)
Methods - Randomisation	8a	Reported method used to generate the random allocation sequence	9 (50)
	8b	Reported randomisation method	13 (72)
	9	Reported mechanism used to implement the random allocation sequence Reported allocation concealment	4 (22) 7 (39)
	10/ ***10a***	Reported who: Generated the random allocation sequence ***Enrolled clusters*** ***Assigned clusters to interventions***	 8 (44) 3 (17) 4 (22)
	10c	***Reported from whom consent was sought*** *Reported whether consent was sought from participants* ***Reported whether consent was sought from clusters*** ***Reported whether participant consent was sought before or after randomisation*** [1]	2 (11) 17 (94) 2 (11) 8/17 (47)
Methods - Blinding	11a	Reported on whether there was blinding Reported who was blinded [2] Reported how they were blinded [2]	10 (56) 6/14 (43) 1/14 (7)
Methods – Analytical methods	***12a***	***Reports clustering accounted for in any of the methods used to address pilot trial objectives/ research questions*** [3]	13/17 (76)
Results – Participant flow	13*	Reports a diagram with flow of individuals through the trial	12 (67)
	13* ***Reports a diagram with flow of clusters through the trial***		10 (56)
	13a/ ***13a*** [S]	Reported number of: Individuals ***(Clusters)*** approached and/or assessed for eligibility [4] Individuals ***(Clusters)*** randomly assigned [4] Individuals ***(Clusters)*** that received intended treatment [4; 4] Individuals ***(Clusters)*** that were assessed for primary objective [4; 4]	 8/17 (47); 10/18 (56) 13/17 (76); 17/18 (94) 8/17 (47); 5/17 (29) 16/17 (94); 14/17 (82)
	13b/ ***13b***	Reported number of: Losses for individuals ***(Clusters)*** after randomisation [4*; 4] Exclusions for individuals ***(Clusters)*** after randomisation [4; 4]	 11/16 (69); 6/17 (35) 1/17 (6); 3/17 (18)
	14a	Reported on dates defining the periods of recruitment	8 (44)

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		Reported on dates defining the periods of follow up	11 (61)
	14b	Reported the pilot trial ended/stopped	0 (0)
Results – Baseline data	15	Reported a table showing baseline characteristics for the individual level If yes, by group	12 (67) 11/12 (92)
	15	***Reported a table showing baseline characteristics for the cluster level*** ***If yes, by group***	2 (11) 2/2 (100)
Results – Outcomes and estimation	17a	Reported results for main feasibility objective (quantitative or qualitative) [5]	13/17 (76)
Results - Harms	19	Reported on harms or unintended effects	4 (22)
	19a [N]	Reported other unintended consequences	0 (0)
Discussion	20 [S]	Reported limitations of pilot trial Reported sources of potential bias Reported remaining uncertainty	17 (94) 10 (56) 10 (56)
	21 [S]	Reported generalisability of pilot trial methods/findings to future definitive trial or other studies	16 (89)
	22	Interpretation of feasibility consistent with main feasibility objectives and findings [5]	12/17 (71)
	22A [N]	Reported implications for progression from the pilot to the future definitive trial	16 (89)
Other information	23	Reported registration number for pilot trial Reported name of registry for pilot trial	11 (61) 11 (61)
	24 [S]	Reported where the pilot trial protocol can be accessed	7 (39)
	25	Reported source of funding	18 (100)
	26 [N]	Reported ethical approval/research review committee approval If yes, reported reference number	17 (94) 8/17 (47)

Item numbers refer to the item in the CONSORT extension for pilot trials (***or for CRTs***) that the item is based on.
[N] represents new items added to the CONSORT extension for pilot trials.
[S] represents items substantially adapted from the CONSORT 2010 for RCTs.
Items specifically relating to the cluster aspect of pilot CRTs are shown in bold italics.
*The CONSORT statements do not include an item 13 but the participant flow subheading strongly recommends a diagram.
[1] Item not relevant for 1 trial [A12] because they said that the Ethics Board determined it could be conducted without informed consent from patients or surrogates.
[2] Item not relevant for 4 trials [A7, A10, A12, A18] because they reported that blinding was not used.
[3] Item not relevant for 1 trial because no confidence intervals/p-values were given,[A17] so clustering did not need to be accounted for in any of their methods because effect estimates are not biased by cluster randomisation, only confidence intervals/p-values.
[4] Not relevant for 1 trial due to the design of the study.[A10] (This paper was different from the others such that it was not relevant to extract these items. The clusters were postcode areas and they were assessing two online recruitment interventions and comparing the success of the recruitment interventions. As such, participants were those who completed the online questions, and each arm of the study had a "total population ranging from 1.6 to 2 million people clustered in 4 postcode areas")
[4*] Not relevant for 2 trials due to the design of these studies.[A10, A12] (See reason above for A10. For A12, data was collected from medical patient charts so these items were not relevant to extract)
[5] One paper reports the feasibility results in a separate paper so is not included.[A3]

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FIGURES

Figure 1: Flow diagram of the identification process for the sample of 18 pilot cluster randomised trials included in this review

APPENDICES

Appendix 1: Search strategy

Appendix 2: Data extracted

Appendix 3: List of studies included in this systematic review

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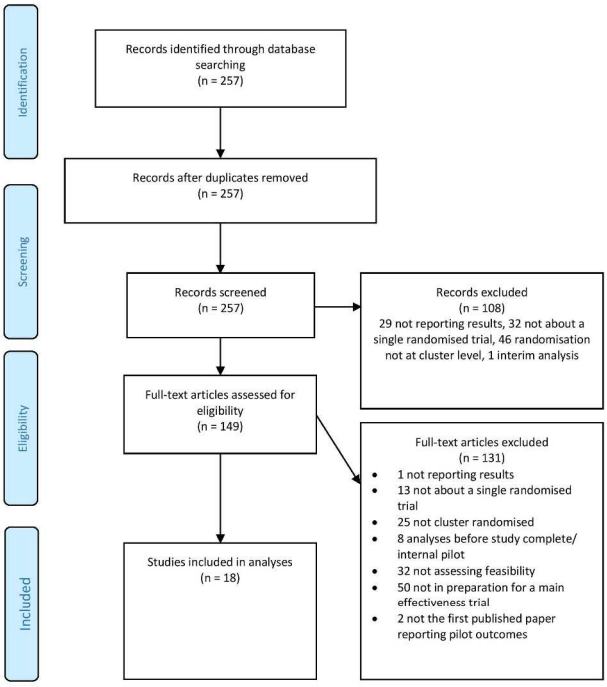

Flow diagram of the identification process for the sample of 18 pilot cluster randomised trials included in this review

210x297mm (300 x 300 DPI)

Appendix 1: Search strategy

#1:	randomised trial [All fields]
#2:	randomized trial [All fields]
#3:	#1 OR #2
#4:	clinical trial [All Fields]
#5:	#3 AND #4
#6:	((cluster randomization) OR (cluster randomisation) OR (cluster) OR (clustered) OR (clustering) OR (clusters) OR (group-randomized) OR (group-randomised) OR (randomisation unit) OR (randomization unit)) [All fields]
#7:	#5 AND #6
#8:	pilot [Title/Abstract]
#9:	feasibility [Title/Abstract]
#10:	#8 OR #9
#11:	#7 AND #10
#12:	protocol [Title]
#13:	#11 NOT #12
#14:	("2011/01/01"[Date - Publication] : "2014/12/31"[Date - Publication])
#15:	#13 AND #14

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Appendix 2: Data extracted

Items	Data extracted	Further information
Descriptives		
Name of first author	Text	
Publication year	Date	The earlier of the print date and electronic date
Journal	Text	
Title	Text	
Country (or countries) in which the trial was set	Text	
Setting where the data were collected	Text	e.g. community, hospital clinic etc.
Pilot trial design	Parallel CRT, factorial CRT, cross-over CRT, other CRT	
What was the cluster?	Text	
Method of cluster randomisation	Text	
Number of clusters randomised	Number	
Number of individuals randomised	Number	
Additional items relating to pilot trial methodology		
Primary objective/ research question of the pilot trial	Text	As specified by the author, else the outcome used in the sample size justification, or else the first objective/ research question mentioned in the abstract or else main text (following a similar method as that used by Diaz-Ordaz et al.[8])
Is the primary objective feasibility?	Yes/No	
Primary objective/ research question measure	Text	
Method used to address primary objective/ research question	Text	Defined as the main method presented for the primary objective/ research question
Main feasibility objective/ research question of the pilot trial	Text	As specified by the author, else the feasibility outcome used in the sample size justification, or else the first feasibility objective/ research question mentioned in the abstract or else main text
Main feasibility objective/ research question measure	Text	
Method used to address main feasibility objective/ research question	Text	Defined as the main method presented for the primary objective/ research question
Is the rationale for numbers in the pilot trial based on formal power calculation for effectiveness (efficacy)?	Yes/no	
Is the paper performing any formal hypothesis testing for effectiveness/ efficacy?	Yes/no	
Is the paper making any statements about effectiveness/ efficacy without a caveat	Yes/no	The caveat must explain that it is an indication of *potential* effectiveness or explain that the study is underpowered
Title and Abstract		
Term 'pilot' or 'feasibility' included in the title	Yes/no	
Identification as a pilot or feasibility randomised trial in the title	Yes/no	Require 'pilot randomised trial' or 'feasibility randomised trial' in the title, or 'pilot study' or 'feasibility study' and 'randomised trial' in the title
Term 'cluster' included in the title	Yes/no	
Identification as a cluster randomised trial in the title	Yes/no	Require 'cluster randomised trial' in the title – don't accept 'clustered' as this can imply correlation rather than cluster randomised
Introduction		
Scientific background and explanation of rationale for future definitive trial reported	Yes/no	
Reasons for randomised pilot trial reported	Yes/no	We specified there needed to be a rationale in the introduction section for the randomised pilot trial, which was not just simply stating the aims/ objectives/outcomes of the pilot trial but gave a clear rationale of why the pilot trial was needed before proceeding to the future definitive trial.

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Rationale given for using cluster design	Yes/no	
Methods – Trial design		
Description of pilot trial design	Yes/no	
Definition of cluster	Yes/no	
Reported any changes to methods after pilot trial commencement If yes, reported reasons	Yes/no Yes/no	
Methods – Participants		
Reported eligibility criteria for participants	Yes/no	
Reported eligibility criteria for clusters	Yes/no	
Reported settings and locations where the data were collected	Yes/no	
Reported how participants were identified	Yes/no	We required that the authors describe the exact way the participants were identified (e.g. during consultations/visits to the cluster, or through advertisement requesting volunteers)
Reported how clusters were identified	Yes/no	We required that the authors describe the exact way the clusters were identified (e.g. all clusters in a particular geographical location, or selection from a register/list etc.)
Reported how participants were consented	Yes/no	
Reported how clusters were consented	Yes/no	
Methods – Interventions		
Described the interventions for each group	Yes/no	
Methods – Outcomes		
Reported any changes to pilot trial assessments or measurements after pilot trial commencement If yes, reported reasons	Yes/no Yes/no	
Reported criteria used to judge whether, or how, to proceed with the future definitive trial	Yes/no	
Methods – Sample size		
Reported a rationale for the sample size of the pilot trial	Yes/no	
Cluster design considered during the description of the rationale for numbers in the pilot trial	Yes/no	
Reported stopping guidelines	Yes/no	
Methods – Randomisation		
Reported method used to generate the random allocation sequence	Yes/no	e.g. random numbers table, coin tossing, computer generated random list
Reported randomisation method If yes, randomisation method	Yes/no Text	e.g. simple, stratification, blocking, matching
Reported mechanism used to implement the random allocation sequence	Yes/no	e.g. sequentially numbered containers, sealed envelopes, central telephone
Reported allocation concealment	Yes/no	
Reported who: Generated the random allocation sequence Enrolled clusters Assigned clusters to interventions	 Yes/no Yes/no Yes/no	 Tick yes for last two points if a 'who' is not relevant since done by e.g. post/online
Reported whether consent was sought from participants	Yes/no	
Reported whether consent was sought from clusters	Yes/no	
Reported from whom consent was sought	Yes/no	I.e. reported both whether consent was sought from participants and whether consent was sought from clusters
Reported whether participant consent was sought before or after randomisation	Yes/no	
Methods – Blinding		
Reported on whether there was blinding	Yes/no	
Reported who was blinded	Yes/no	tick yes if they report anyone who was blinded, even if they don't report on everyone
Reported how they were blinded	Yes/no	tick yes if they report on how anyone was blinded, even if they don't report on how everyone who was blinded was blinded
Methods – Analytical methods		

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Reports clustering accounted for in any of the methods used to address pilot trial objectives/ research questions	Yes/no	
Results – Participant flow		
Reports a diagram with flow of individuals through the trial	Yes/no	
Reports a diagram with flow of clusters through the trial	Yes/no	
Reported number of: Individuals approached and/or assessed for eligibility Individuals randomly assigned Individuals that received intended treatment Losses for individuals after randomisation Exclusions for individuals after randomisation Individuals that were assessed for primary objective	 Yes/no Yes/no Yes/no Yes/no Yes/no Yes/no	
Reported number of: Clusters approached and/or assessed for eligibility Clusters randomly assigned Clusters that received intended treatment Losses for clusters after randomisation Exclusions for clusters after randomisation Clusters that were assessed for primary objective	 Yes/no Yes/no Yes/no Yes/no Yes/no Yes/no	
Results – Recruitment		
Reported on dates defining the periods of recruitment	Yes/no	
Reported on dates defining the periods of follow up	Yes/no	
Reported the pilot trial ended/stopped	Yes/no	
Results – Baseline data		
Reported a table showing baseline characteristics for the individual level If yes, by group	Yes/no Yes/no	
Reported a table showing baseline characteristics for the cluster level If yes, by group	Yes/no Yes/no	
Results – Outcomes and estimation		
Reported results for main feasibility objective (quantitative or qualitative)	Yes/no	
Results – Harms		
Reported on harms or unintended effects	Yes/no	Tick yes even if reported that there were no harms
Reported other unintended consequences	Yes/no	An unintended consequence would be an unexpected result/finding that was not one of the objectives to explore and where the result would have consequences on the future definitive trial, such as a change in design/population etc.
Discussion		
Reported limitations of pilot trial	Yes/no	
Reported sources of potential bias	Yes/no	
Reported remaining uncertainty	Yes/no	
Reported generalisability of pilot trial methods/findings to future definitive trial or other studies	Yes/no	To be reporting on the generalisability of the pilot trial methods/findings to the future definitive trial, we deemed it sufficient for the paper to be discussing whether the methods/findings of the pilot study can be applied to the future definitive trial. To be reporting on the generalisability of the pilot trial methods/findings to other future trials, we deemed it sufficient for the paper to be discussing whether the methods/findings of the pilot study can be applied to other future trials.
Interpretation of feasibility consistent with main feasibility objectives and findings	Yes/no	
Reported implications for progression from the pilot to the future definitive trial If yes, what were the implications?	Yes/no Proceed/ proceed with changes/ Further	

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	research or piloting needed first/ Don't go ahead	
Other information		
Reported registration number for pilot trial	Yes/no	
Reported name of registry for pilot trial	Yes/no	
Reported where the pilot trial protocol can be accessed	Yes/no	
Reported source of funding	Yes/no	
Reported ethical approval/research review committee approval If yes, reported reference number	Yes/no Yes/no	

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PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	1, 2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	3
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	3
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	5
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	3, 4
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	4
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Appendix 1
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	4
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	5, 6
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	Appendix 2
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	N/A – review of reporting quality
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	N/A –

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			review of reporting quality
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	N/A – review of reporting quality

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	N/A – review of reporting quality
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	N/A – review of reporting quality
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	6, 7, Figure 1
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	7, Table 1, Appendix 3
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	N/A – review of reporting quality
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	N/A – review of reporting

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PRISMA 2009 Checklist

			quality
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	N/A – review of reporting quality
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	N/A – review of reporting quality
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	N/A – review of reporting quality
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	9, 10, 11
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	12
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	11
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	13

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

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The Quality of Reporting of Pilot and Feasibility Cluster Randomised Trials: A Systematic Review

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ABSTRACT

Background: There are an increasing number of studies described as pilot and feasibility studies. Reporting is generally poor. These studies are particularly important when designing cluster randomised trials (CRTs).

Objectives: To systematically review the quality of reporting of pilot and feasibility CRTs. In particular, to assess (1) the number of pilot CRTs conducted between 01/01/2011 and 31/12/2014, (2) whether objectives and methods are appropriate and (3) reporting quality.

Methods: We searched PubMed (2011-2014) for CRTs with 'pilot' or 'feasibility' in the title or abstract; that were assessing some element of feasibility; and showing evidence the study was in preparation for a main effectiveness/efficacy trial. Quality assessment criteria were based on the Consolidated Standards of Reporting Trials (CONSORT) extensions for pilot trials and CRTs.

Results: Eighteen pilot CRTs were identified. Forty-four percent did not have feasibility as their primary objective, and many (50%) performed formal hypothesis testing for effectiveness/efficacy despite being underpowered. Most (83%) included 'pilot' or 'feasibility' in the title, and discussed implications for progression from the pilot to the future definitive trial (89%), but fewer reported reasons for the randomised pilot trial (39%), sample size rationale (44%), or progression criteria (17%). Most defined the cluster (100%), and number of clusters randomised (94%), but few reported

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how the cluster design affected sample size (17%), whether consent was sought from clusters (11%), or who enrolled clusters (17%).

Conclusions: That only 18 pilot CRTs were identified necessitates increased awareness of the importance of conducting and publishing pilot CRTs and improved reporting. Pilot CRTs should primarily be assessing feasibility, avoiding formal hypothesis testing for effectiveness/efficacy, and reporting reasons for the pilot, sample size rationale, and progression criteria, as well as enrolment of clusters, and how the cluster design affects design aspects. We recommend adherence to the CONSORT extensions for pilot trials and CRTs.

Article summary

Strengths and limitations of this study

- We used a robust search and data extraction procedure, including validation of the screening/sifting process and double data extraction.
- We may have missed some studies, since our criteria excluded studies not including 'pilot' or 'feasibility' in the title or abstract, and those not clearly in preparation for a main trial.

BACKGROUND

In a cluster randomised trial (CRT) clusters, rather than individuals, are the units of randomisation. A cluster is a group (usually predefined) of one or more individuals. For example, clusters could be hospitals and the individuals, the patients within those hospitals. CRTs are often chosen for logistical reasons, prevention of contamination across individuals, or because the intervention is targeted at the cluster level. CRTs are useful for evaluating complex interventions. However, they have added complexity in terms of design, implementation, and analysis and so it is important to ensure that carrying out a CRT is feasible before conducting the future definitive trial.[1]

A feasibility study conducted in advance of a future definitive trial is a study designed to answer the question about whether the study can be done and whether one should proceed with it. A pilot study answers the same question but in such a study part or all of the future trial is carried out on a smaller scale.[2] Thus all pilot studies are also feasibility studies. Pilot studies can be randomised or

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non-randomised; for brevity we use the term pilot CRT throughout this paper to refer to a randomised study with a clustered design that is in preparation for a future definitive trial assessing effectiveness/efficacy.[3, 4] The focus of pilot trials is on investigating areas of uncertainty about the future definitive trial to see whether it is feasible to carry out, so the data, methods, and analysis are different from an effectiveness/efficacy trial. In particular, more data might be collected on items such as recruitment and retention to assess feasibility, methods may include specifying criteria to judge whether to proceed with the future definitive trial, and analysis is likely to be based on descriptive statistics since the study is not powered for formal hypothesis testing for effectiveness/efficacy.

Arnold et al. highlight the importance of pilot studies being of high quality.[5] Good reporting quality is essential to show how the pilot has informed the future definitive trial as well as to allow readers to use the results in preparing for similar future trials. The number of pilot and feasibility studies in the literature is increasing. However, Arain et al. indicate that reporting of pilot studies is poor.[6] There are no previous reviews of the reporting quality of pilot CRTs, despite the extra complications arising from the clustered structure. The aim of this review is to reveal the quality of reporting of pilot CRTs published between 01/01/2011 and 31/12/2014. We extracted information to describe the sample of pilot CRTS and to assess quality, with quality criteria based on the Consolidated Standards of Reporting Trials (CONSORT) extension for CRTs,[7] and a CONSORT extension for pilot trials which SE and CC were involved in the final stages of development of during this review.[3, 4] We present recommendations for improving the conduct, analysis and reporting of these studies and expect this to improve the quality, usefulness and interpretation of pilot CRTs in the future. We know current reporting of CRTs is suboptimal,[8-11] and thus we expected the reporting of pilot CRTs to be even poorer.

The questions addressed by this review are:

1) How many pilot CRTs have been conducted between 01/01/2011 and 31/12/2014?
2) Are pilot CRTs using appropriate objectives and methods?
3) To what extent is the quality of reporting of pilot CRTs sufficient?

METHODS

Inclusion and exclusion criteria

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We included papers published in English with a publication date (print or electronic) between 01/01/2011 and 31/12/2014. We chose the start date to be after the updated CONSORT 2010 was published.[12] We estimated a search covering four years would give us a reasonable number of papers to perform our quality assessment, and that later papers would be similar in terms of quality of reporting since the CONSORT for pilot trials was not published until the end of 2016. The study had to be a CRT, have the word 'pilot' or 'feasibility' in the title or abstract, be assessing some element of feasibility, and show evidence that the study was in preparation for a specific trial assessing effectiveness/efficacy that is planned to go ahead if the pilot trial suggests it is feasible (i.e. not just a general assessment of feasibility issues to help researchers in general, although pilot trials may do this as an addition). Regardless of how authors described a study, we did not consider it to be a pilot trial if it was *only* looking at effectiveness/efficacy because we wanted to exclude those studies that claim to be a pilot/feasibility trial simply as justification for small sample size.[13] The paper had to be reporting results (i.e. not a protocol or statistical analysis plan) and had to be the first published paper reporting pilot outcomes (i.e. not an extension/follow-up study for a pilot study already reported, and not a second paper reporting further pilot outcomes). Interim analyses, analyses before the study was complete, and internal pilots were excluded; the CONSORT extension for pilot trials on which we based the quality assessment does not apply to internal pilots.[3, 4] No studies were excluded on the basis of quality since the aim was to assess the quality of reporting.

Data sources and search methods

We searched PubMed for relevant papers in September 2015. We searched for the words 'pilot' or 'feasibility' in the title or abstract, a search strategy similar to that used by Lancaster et al. [14] We combined this with a search strategy to identify CRTs; this was similar to the strategy used by Diaz-Ordaz et al. [8] The full electronic search strategy is given in Appendix 1.

Sifting and validation

The titles and abstracts of all papers identified by the electronic search were screened by CC for possible inclusion. Full texts were obtained for those papers identified as definitely or possibly satisfying the inclusion criteria and sifted by CC for inclusion. As validation, CL carried out the same screening and sifting process independently on a 10% random sample of electronically identified papers. For full texts where there was uncertainty whether the paper should be included, it was referred to SE for a final decision.

Refining the inclusion process

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We refined the screening and sifting process following piloting. In particular we rejected a more restrictive PubMed search that required 'pilot' or 'feasibility' in the title rather than allowing these words to occur in the title *or* abstract because this missed relevant papers; we altered the order of the exclusion criteria to make the process more streamline; and we relaxed one inclusion criteria, requiring evidence that the pilot trial was in preparation for a future definitive trial rather than an explicit statement that authors were planning a future definitive trial. The protocol was updated, and is available from the corresponding author.

Data Extraction

CC and CL independently extracted data from all papers selected for inclusion in the review, and followed rules on what to extract (see Further information column of Appendix 2). Extracted data were recorded in an Excel spreadsheet. Discrepancies were resolved by discussion between CC and CL, and where agreement could not be reached a final decision was made by SE.

For each pilot CRT included in the review, we extracted information to describe the trials, including publication date (print date unless there was an earlier electronic date), country in which the trial was set, number of clusters randomised, method of cluster randomisation and, following the CONSORT extension for pilot trials' recommendation to focus on objectives rather than outcomes, the primary objective. We defined the primary objective using method similar to that used by Diaz-Ordaz *et al*.[8] for primary outcomes i.e. as that specified by the author, else the objective used in the sample size justification, or else the first objective mentioned in the abstract or else main text.

To assess whether the pilot trials were using appropriate objectives and methods, we collected information on whether the primary objective was about feasibility, the method used to address the main feasibility objective, the rationale for numbers in the pilot trial, and whether there was formal hypothesis testing for, or statements about, effectiveness/efficacy without a caveat about the small sample size.

To assess reporting quality, we created a list of quality assessment items based on the CONSORT extension for pilot trials.[3, 4] We also looked at the CONSORT extension for CRTs,[7] and incorporated any cluster-specific items into our quality assessment items. Where a CRT item became less relevant in the context of a pilot trial, we did not extract it (e.g. whether variation in cluster sizes was formally considered in the sample size calculation). In addition, where there was a substantial difference between the item for the CONSORT extension for CRTs and that for the pilot trial

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extension and the items were not compatible, we used the latter item (e.g. focusing on objectives rather than outcomes). We recognised the need to balance comprehensiveness and feasibility.[11] Therefore, where items referred to objectives or methods, we extracted this for the primary objective only. We also did not extract on whether papers reported a structured summary of trial design, methods, results, and conclusions. The final version of the full list of data extracted, and further information on each item extracted, is included in Appendix 2.

Refining data extraction

Initially CC extracted data on a random 10% sample of papers. However, some of the items were difficult to extract in a clear, standardised way, as similarly noted by Ivers et al,[11] so these items were removed. In particular: whether the objectives, intervention, or allocation concealment were at the individual level, cluster level, or both; and other analyses performed or other unintended consequences (difficult to decipher from papers whether it classified as an 'other'). Furthermore, some items were deemed easier to extract if split into two items, for example; 'reported why the pilot trial ended/stopped' which we subsequently split into 'reported the pilot trial ended/stopped' and 'if so, what was the reason'.

Analysis

Data were analysed using Excel version 2013. We describe the characteristics of the pilot CRTs using descriptive statistics. Where we extracted text, we established categories during analysis by grouping similar data, for example grouping the different primary objectives. To assess adherence to the CONSORT checklists, we present the number and percentage reporting each item. This report adheres, where appropriate, to the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) statement.[15]

Patient involvement

No patients were involved in the development of the research question, design or conduct of the study, interpretation or reporting. No patients were recruited for this study. There are no plans to disseminate results of the research to study participants.

RESULTS

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The electronic PubMed search identified 257 published papers. We rejected 108 during screening (29 not reporting results; 32 not about a single randomised trial; 46 not cluster randomised; 1 interim analysis). The remaining 149 full-text articles were assessed for eligibility, and 131 more papers were rejected (1 not reporting results; 13 not about a single randomised trial; 25 not cluster randomised; 8 analyses before study complete/internal pilot; 32 not assessing feasibility; 50 not in preparation for a future definitive effectiveness/efficacy trial; 2 not the first published paper reporting pilot outcomes). This left 18 studies to be included in the analysis.[A1-A18]. The full list of studies is included in Table 1, with citations in Appendix 3. Figure 1 shows the flow diagram of the identification process for the sample of 18 pilot CRTs.

There was 96% agreement between CC and CL for the 10% random sample used for the screening and sifting validation (based on 26 papers), with a kappa coefficient of 0.84.

Trial characteristics

In general, the more recent the publication date, the more pilot CRTs were identified, but with the most identified in 2013 (Table 2). Of the 18 included studies, the majority (56%) were set in the UK. All other countries were represented only once except for Canada (3 trials) and USA (2 trials). Of those reporting the method of randomisation, the majority (69%) used stratified with blocked randomisation. The median number of clusters randomised was 8 (IQR: 4 to 16) with a range from 2 to 50.

Pilot trial objectives and methods

Ten (56%) of the 18 included pilot trials had feasibility as their primary objective, for example assessing feasibility of implementing the intervention (6 trials), of recruitment and retention (3 trials), and of the cluster design (1 trial) (Table 3). All ten trials reported a corresponding measure to assess the feasibility objective; most (90%) used descriptive statistics and/or qualitative methods to address the objective. In one trial a statistical test was used to address their primary feasibility objective without the authors designing the study to be adequately powered to do so.

The remaining eight trials had an effectiveness/efficacy primary objective, and used statistical tests to address this. Nevertheless these eight trials all had feasibility as one of their other objectives (this was an inclusion criterion). The feasibility objectives were similar to those where the feasibility was primary, but expressed more generally in two trials, for example, looking at the feasibility of the future definitive trial,[A16] and looking at whether the future definitive trial could answer the

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effectiveness question and which study design would enable this.[A10] In only three trials was a measure to assess the feasibility objective reported, using either quantitative or qualitative measures.

Eight trials reported a rationale for the numbers in the pilot trial, with all of these following best practice in not basing the rationale on a formal sample size calculation for effectiveness/efficacy. Nine (50%) trials performed any formal hypothesis testing for effectiveness/efficacy, regardless of whether this was for the primary or a secondary objective. Of these nine trials, four of the conclusions about effectiveness/efficacy were made without any caveats about the imprecision of estimates or possible lack of representativeness because of the small samples.

Quality of reporting – by items

The pilot CRTs in our review are published after the CONSORT 2010 for RCTs but before the CONSORT extension for pilot trials. Therefore, to present data on quality of reporting, we looked at our list of quality assessment items based on the CONSORT extension for pilot trials, and grouped reporting items into three categories (Table 4): (1) items in the CONSORT extension for pilot trials that are new compared to CONSORT 2010 for RCTs, (2) items in the CONSORT extension for pilot trials that are substantially adapted from CONSORT 2010 for RCTs and (3) items in the CONSORT extension for pilot trials that are the same as or have only minor differences from CONSORT 2010 for RCTs, plus items in the CONSORT extension for CRTs.[3, 4, 7, 12]

In the tables, denominators for proportions are based on papers for which the item is relevant. Not all items are relevant for all trials, due to their design, so we highlight where this applies in the table footnotes.

New items

Five new items were added to the CONSORT extension for pilot trials on the identification and consent process, progression criteria, other unintended consequences, implications for progression, and ethical approval.[3, 4] In our review, how participants were identified and consented was reported by 50% and 76% of the pilot CRTs, respectively, but how clusters were identified and consented was reported by just 33% and 11%, respectively. Only 3 trials (17%) reported criteria used to judge whether or how to proceed with the future definitive trial, with two giving numbers that must be exceeded such as recruitment, retention, attendance, and data collection percentages,[A17,

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A2] and one giving categories of “definitely feasible”, “possibly feasible”, and “not feasible”.[A12] The item on other unintended consequences was reported by none of the pilot CRTs, although it is unclear whether this is due to poor reporting or because no unintended consequences occurred. Implications for progression from pilot to future definitive trial was reported by 16 trials (89%), with nine reporting to proceed/proceed with changes, five reporting further research or piloting is needed first, and two reporting to not go ahead with the future definitive trial. 94% reported ethical approval/research review committee approval, but only 47% of them also reported the corresponding reference number.

Substantially adapted items

Six items in the CONSORT extension for pilot trials were substantially adapted from CONSORT 2010 for RCTs, regarding reasons for the randomised pilot trial, sample size rationale for the pilot trial, numbers approached and/or assessed for eligibility, remaining uncertainty about feasibility, generalisability of pilot trial methods and findings, and where the pilot trial protocol can be accessed.[3, 4] Reasons for the randomised pilot trial were reported by 39% of the pilot CRTs. Eight trials (44%) gave a rationale for the sample size of the pilot trial. Pilot trials should always report a rationale for their sample size; this can be qualitative or quantitative, but shouldn’t be based on a formal sample size calculation for effectiveness/efficacy. In this review, the rationales were based on logistics,[A15] resources,[A14] time,[A16] a balance of practicalities and need for reasonable precision,[A18] a general statement that it was considered sufficient to address the objectives of the pilot trial,[A17] formal [A6] and non-formal [A7] calculation to enable estimation of parameters in the future definitive trial, and a formal calculation based on the primary feasibility outcome.[A12] Of these rationales, good examples include “The decision to include eight apartment-sharing communities was based on practical feasibility that seemed appropriate according to funding and the personal resources available”,[A14] as well as “The sample size was chosen in order to have two clusters per randomized treatment and the number of participants per cluster was based on the number of degrees of freedom needed within each cluster to have reasonable precision to estimate a variance”.[A6] The number of individuals approached and/or assessed for eligibility was reported by 47%, and the number of clusters by 56%. Remaining uncertainty was reported by 56% of the pilot CRTs. 89% reported generalisability of pilot trial methods/findings to the future definitive trial or other studies, but clarity of reporting was lacking as it was difficult to distinguish between references to the future definitive trial versus other future studies due to ambiguous phrases such as “in a future trial”. Only 39% reported where the pilot trial protocol could be accessed.

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Items essentially taken from CONSORT 2010 for RCTs or the CONSORT extension for CRTs

For the remaining items, reporting quality was variable. Some were reported by fewer than 20% of the pilot CRTs, for example considering the cluster design in the sample size rationale for the pilot trial (17%), reporting whether consent was sought from clusters (11%) and who enrolled them (17%), how people were blinded (7% of applicable trials), number of excluded individuals (6% of applicable trials) and clusters (18% of applicable trials) after randomisation, and a table showing baseline cluster characteristics (11%). Those reported most well, by more than 80% of the pilot CRTs, included reporting 'pilot' or 'feasibility' in the title (83%), scientific background and explanation of rationale for future definitive trial (100%), pilot trial design (100%), nature of the cluster (100%), settings and locations where the data were collected (100%), whether consent was sought from participants (94%), number of clusters randomised (94%) and assessed for primary objective (82% of applicable trials), number of individuals assessed for primary objective (94% of applicable trials), limitations of pilot trial (94%), and source of funding (100%).

Quality of reporting – by study

Finally, in Table 5 we present the number (percentage) of quality assessment items reported by each study. We provide an overall score, as well as a score by categories of CONSORT. The quality of reporting varies across studies, with 5 of the pilot CRTs reporting over 65% of the quality assessment items and 2 of the pilot CRTs reporting under 30%. There does not appear to be a trend of reporting quality with time. Five of the studies report 90% or more of the quality assessment items in the 'discussion and other information' category, and only two studies report less than 50%. Two of the studies report 100% of the items in the 'title and abstract and introduction' category, and five studies report less than 50%. The highest percentage of items reported by a study in the 'methods' category is 66% and the lowest is 14%. Similarly, the highest percentage of items reported by a study in the 'results' category is 78% and the lowest is 18%. Within studies, the category that is best reported tends to be the 'discussion and other information' category (had the highest percentage for 10 of the 18 pilot CRTs).

DISCUSSION

Main findings

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This is the first study to assess the reporting quality of pilot CRTs using the recently developed CONSORT checklist for pilot trials.[3, 4] Our search strategy and inclusion criteria identified 18 pilot CRTs published between 2011 and 2014. Most studies were published in the UK, perhaps driven by the availability of funding or the large number of CRTs and interest in complex interventions in the UK.

With respect to the pilot CRT objectives and methods, a considerable proportion of papers did not have feasibility as their primary objective. Of the trials reporting a sample size rationale for the pilot, all followed best practice in not carrying out a formal sample size calculation for effectiveness/efficacy, yet a substantial proportion performed formal hypothesis testing for effectiveness/efficacy. This could indicate an inappropriate attachment to hypothesis testing, although many did explain it was an indication of *potential* effectiveness or that the study was underpowered. Investigators wanting to assess effectiveness/efficacy and use statistical tests to do so should be performing a properly powered definitive trial, otherwise there is the potential for misleading conclusions affecting clinical decisions as well as misinformed decisions about the future definitive trial.[16] One may however look at *potential* effectiveness, for example using an interim or surrogate outcome, with a caveat about the lack of power.[3, 4] Moreover, one may include a progression criterion based on potential effect. If so, Eldridge and Kerry recommend any interpretation of potential effect is done by looking at the limits of the confidence interval,[13] and one should also pay attention to features of the pilot which might have biased the result (for example, convenience sampling of clusters). A positive effect finding excluding the null value would still justify the future definitive trial to estimate the effect with greater certainty, but a negative effect finding excluding the null value (i.e. strongly suggesting harm), or even a finding where the clinically important difference is excluded, might suggest not proceeding. It is good practice to pre-state such progression criteria. Finally, one may use estimates from outcome data, for example, as inputs for the sample size calculation for the future definitive trial. In particular, for pilot CRTs we may be interested in estimating the intra-cluster correlation coefficient (ICC), although we note that the ICC estimate from a pilot CRT should not be the only source for the future definitive trial sample size, because of the large amount of imprecision in a pilot trial.[17] Reporting quality of pilot CRTs was variable. Items reported well included reporting the term ‘pilot’ or ‘feasibility’ in the title, generalisability of pilot trial methods/findings to the future definitive trial or other studies, and implications for progression from the pilot to the future definitive trial, although clarity could be improved when referring to the future definitive trial rather than other future studies in general. Items least well reported included reasons for the randomised pilot trial, sample size rationale for

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the pilot trial, criteria used to judge whether or how to proceed with the future definitive trial, and where the pilot trial protocol can be accessed. These items are important so that readers can understand whether the uncertainty they are facing about their future trial has already been addressed in a pilot, researchers can make sure they have enough patients to achieve the pilot trial objectives, readers can understand the criteria for progression, and to prevent against selective reporting.

For items related to the cluster aspect of pilot CRTs, most pilot CRTs reported the nature of the cluster, and the number of clusters randomised and assessed for the primary objective. The items reported least well included considering the cluster design during the sample size rationale for the pilot trial, reporting who enrolled clusters and how they were consented, number of exclusions for clusters after randomisation, and a table showing baseline cluster characteristics. Although the number of clusters in a pilot trial is usually small it is still important to, for example, describe the cluster-level characteristics using a baseline table as it may give helpful information important for planning the future definitive trial. Moreover, while nearly all trial reports described whether consent was sought from individuals or not, seeking agreement from clusters was only described in a small minority. The items on agreement from and enrolment of clusters, baseline cluster characteristics, and number of excluded clusters are particularly important to report, since they may affect assessment of feasibility.

If we consider why some items may have been well adhered to and others not, it is interesting to observe that new items added to the CONSORT extension for pilot trials and items substantially adapted from CONSORT 2010 for RCTs were in general not well adhered to. This could perhaps be because of somewhat newer ideas that may not have been considered during design such as specifying progression criteria and considering a rationale for numbers in the pilot. Alternatively, perhaps there were aspects sometimes done but not reported due to lack of reporting guidance to remind authors; for example, the new items on how clusters were identified and consented, other unintended consequences, and ethical approval/research review committee approval reference number, and the substantially adapted items on reporting reasons for the pilot trial, number of individuals approached and/or assessed for eligibility, and where the pilot trial protocol can be accessed. With the item on unintended consequences, we recognise that investigators are free to choose what they interpret and report as an unintended consequence. We recommend careful thought that all unintended consequences that may affect the future definitive trial are reported. It is also interesting to observe that many of the most poorly reported items concerned

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methods/design (progression criteria; enrolment and consent of clusters), and in particular, justification of design aspects (reasons for randomised pilot trial; sample size rationale for pilot trial including consideration of cluster design). Within studies, the category that is worst reported is the methods, despite being crucial to allow the reader to judge the quality of the trial.

Comparison with other studies

There has not been a previous review of pilot trials using the new CONSORT extension for these trials.[3, 4] However, the review by Arain et al. looking at pilot and feasibility studies reported that 81% were performing hypothesis testing with sample sizes known to be insufficient,[6] compared to 50% of pilot CRTs in our review. Arain et al. also reported 36% of studies performing sample size calculations for the pilot. In our review, 17% performed calculations (all based on feasibility objectives), but if we include those that also correctly reported a rationale for the numbers in the pilot but without any calculation then this was 44%.

The general message that reporting of CRTs is suboptimal still holds.[8-11] The review by Diaz-Ordaz et al. (2013) of definitive trial CRTs reported that 37% presented a table showing baseline cluster characteristics, compared to 11% of pilot CRTs in our review. Diaz-Ordaz et al. (2013) also reported that 27% accounted for clustering in sample size calculations,[8] and a recent review by Fiero et al. reported 53%.[10] However, just 17% of pilot CRTs in our review considered the cluster design in the sample size rationale for the pilot trial. Both these CRT reviews reviewed effectiveness/efficacy CRTs, for which the need to take account of clustering in sample sizes is generally well understood compared to pilot trials. In pilot trials the rationale for considering the clustered design in deciding on numbers in the pilot may be different, for example, considering the number of degrees of freedom needed within each cluster to estimate a variance.[A6] In pilot trials, including a number of clusters with different characteristics may also be important to get an idea about the implementation of an intervention across different clusters.

Strengths and limitations

We used a robust search and data extraction procedure, including validation of the screening/sifting process and double data extraction. However, the use of only one database, PubMed, which is comprehensive but not exhaustive, may have missed eligible papers, and the use of conditions #3, #5, and #6 (see Appendix 1) may have been restrictive. Our aim was to get a general idea of reporting issues in the area, though, rather than doing a completely comprehensive search. Our inclusion criteria stipulated that papers must have the word ‘pilot’ or ‘feasibility’ in the title or

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abstract, so we may have missed some pilot CRTs and thus may have overestimated the percentage reporting 'pilot' or 'feasibility' in the title. This strategy may also have resulted in a skewed sample of papers with a greater tendency to adhere to CONSORT guidelines. However, our review suggests reporting of pilot CRTs need improving, so our conclusion would remain the same. We required authors to report that the trial was in preparation for a future definitive trial, so we expect that items related to the future definitive trial (e.g. progression criteria, generalisability, implications) may be better reported than they would for all publications of pilot CRTs which might include papers that did not report that they were in preparation for a future definitive trial clearly enough to be included. During sifting, we identified 32 trials that had 'pilot' or 'feasibility' in the title/abstract, but were not assessing feasibility. A third of these were identified because they referred to 'pilot' or 'feasibility' at some point in the abstract but it was not in reference to the current trial (e.g. stating feasibility has already been shown), but the other two thirds were labelled as a pilot or feasibility trial yet showed no evidence of assessing feasibility and were only assessing effectiveness. This is an important point as our review may appear to overestimate reporting quality by not including these studies. That there are underpowered main trials being published as pilot or feasibility studies is something that the academic community should look to prevent. During sifting, we also identified 50 trials that were assessing feasibility but did not show evidence of being in preparation for a future definitive trial. Most were assessing the feasibility of implementing an intervention targeted at members of the public, or discussing feasibility of the intervention with the aim of providing information to help researchers wanting to implement a similar intervention in similar settings or to raise questions for future research, rather than being in preparation for a trial assessing effectiveness/efficacy. Some of these 50 trials also appeared to be small effectiveness studies labelled as a pilot, usually only mentioning feasibility once or twice throughout the paper, with one trial explicitly stating that "Because of organizational changes… we had to stop the inclusion after 46 participants, and the study is consequently defined as a pilot study."[18] For the few trials that were potentially pilot CRTs not reported clearly enough, authors only spoke of future studies in general rather than clearly specifying the study was in preparation for a specific future definitive trial. Related to this, it is of interest to know the proportion of our 18 pilot CRTs that are actually followed by a future definitive trial, and we plan to investigate this in future.

CONCLUSION

We may have overestimated the reporting quality of pilot CRTs; nevertheless our review demonstrates that reporting of pilot CRTs need improving. The identification of just 18 pilot CRTs

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between 2011 and 2014, mainly from the UK, highlights the need for increased awareness of the importance of carrying out and publishing pilot CRTs and good reporting so that these studies can be identified. Pilot CRTs should primarily be assessing feasibility, and avoiding formal hypothesis testing for effectiveness/efficacy. Improvement is needed in reporting reasons for the pilot, rationale for the pilot trial sample size, and progression criteria, as well as the enrolment stage of clusters and how the cluster design affects aspects of design such as numbers of participants. We recommend adherence to the new CONSORT extension for pilot trials, in conjunction with the CONSORT extension for CRTs.[3, 4, 7] We encourage journals to endorse the CONSORT statement, including extensions.

CONTRIBUTORS:

SE conceived the study and advised on the design and protocol. CC developed the design of the study, wrote the protocol, and designed the screening/sifting and data extraction sheet. CC performed screening and sifting on all papers identified by the electronic search, and CL carried out validation of the screening/sifting process. CC and CL performed independent data extraction on all papers included in the review. CC conducted the analyses of the data and took primary responsibility for writing the manuscript. All authors provided feedback on all versions of the paper. All authors read and approved the final manuscript. CC is the study guarantor.

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All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare that CC was funded by an NIHR Research Methods Fellowship during this project, and that SE and CC are authors on the new CONSORT extension for pilot trials.

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Extraction data are available from the corresponding author.

TRANSPARENCY DECLARATION:

This manuscript is an honest, accurate, and transparent account of the study being reported. No important aspects of the study have been omitted, and any discrepancies from the study as planned have been explained.

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TABLES

Table 1: Pilot CRTs included in this review

Author	Year*	Journal	Title	Cluster
Begh [A1]	2011	Trials	Promoting smoking cessation in Pakistani and Bangladeshi men in the UK: pilot cluster randomised controlled trial of trained community outreach workers	Census lower layer super output areas
Jones [A2]	2011	Pediatric Exercise Science	Promoting fundamental movement skill development and physical activity in early childhood settings: a cluster randomized controlled trial.	Childcare centers
Légaré [A3]	2010	Health Expectations	Training family physicians in shared decision making for the use of antibiotics for acute respiratory infections: a pilot clustered randomized controlled trial.	Family medicine groups
Hopkins [A4]	2012	Health Education Research	Implementing organizational physical activity and healthy eating strategies on paid time: process evaluation of the UCLA WORKING pilot study	Worksites - health and human service organizations
Jago [A5]	2012	International Journal of Behavioral Nutrition and Physical Activity	Bristol girls dance project feasibility trial: outcome and process evaluation results	Secondary schools
Taylor [A6]	2011	Clinical Rehabilitation	A pilot cluster randomized controlled trial of structured goal-setting following stroke	Rehabilitation services
Drahota [A7]	2013	Age and Ageing	Pilot cluster randomised controlled trial of flooring to reduce injuries from falls in wards for older people.	Study areas - bays within hospitals
Frenn [A8]	2013	Journal for Specialists in Pediatric Nursing	Authoritative feeding behaviors to reduce child BMI through online interventions	Classrooms
Gifford [A9]	2012	World Views on Evidence-Based Nursing	Developing leadership capacity for guideline use: a pilot cluster randomized control trial.	Service delivery centers with nursing care for diabetic foot ulcers
Jones [A10]	2013	Journal of Medical Internet Research	Recruitment to online therapies for depression: pilot cluster randomized controlled trial.	Postcode areas
Moore [A11]	2013	Substance Abuse Treatment, Prevention, and Policy	An exploratory cluster randomised trial of a university halls of residence based social norms marketing campaign to reduce alcohol consumption among 1st year students.	Residence halls
Pai [A12]	2013	Implementation Science	Strategies to enhance venous thromboprophylaxis in hospitalized medical patients (SENTRY): a pilot cluster randomized trial	Hospitals
Reeves [A13]	2013	BMC Health Services Research	Facilitated patient experience feedback can improve nursing care: a pilot study for a phase III cluster randomised controlled trial.	Wards
Teut [A14]	2013	Clinical Interventions in Aging	Effects and feasibility of an Integrative Medicine program for geriatric patients-a cluster-randomized pilot study.	Shared apartments
Jago [A15]	2014	International Journal of Behavioral Nutrition and Physical Activity	Randomised feasibility trial of a teaching assistant led extracurricular physical activity intervention for 9 to 11 year olds: Action 3:30	Primary schools
Michie [A16]	2014	Contraception	Pharmacy-based interventions for initiating effective contraception following the use of emergency contraception: a pilot study	Pharmacies
Mytton [A17]	2014	Health Technology Assessment	The feasibility of using a parenting programme for the prevention of unintentional home injuries in the under-fives: a cluster randomised controlled trial.	Children's centres
Thomas [A18]	2014	Trials	Identifying continence options after stroke (ICONS): a cluster randomised controlled feasibility trial	Stroke services

* We extracted the earlier of the print and electronic publication year.

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Table 2: Characteristics of pilot CRTs included in this review

Characteristic	Number of trials (%)
Publication year (earlier of the print and electronic publication date)	
2010[a]	1 (6)
2011	3 (17)
2012	3 (17)
2013	7 (39)
2014	4 (22)
Country	
UK	10 (56)
Canada	3 (17)
USA	2 (11)
Germany	1 (6)
New Zealand	1 (6)
Australia	1 (6)
Method of cluster randomisation[b]	
Simple	1 (8)
Stratified with blocks	9 (69)
Blocked only	2 (15)
Bias coin method	1 (8)
Number of clusters randomised[c]	
Median (IQR)	8 (4 to 16)
Range	2 to 50
Average cluster size[d]	
Median (IQR)	32 (14 to 82)
Range	7 to 588

[a] 1 paper has an extracted publication year outside of the 2011 to 2014 range. This is because the print publication date for this paper was 2011 but the online publication date was 2010, so the paper satisfies the inclusion criteria which states that the publication date, print **or** electronic, must be between 2011 and 2014, but we extract the earlier of the print and electronic dates.

[b] 13 of the 18 trials reported their method of randomisation. Percentages are given as a percentage of these 13 trials.

[c] Not reported for 1 trial.

[d] Defined as number of individuals randomised divided by number of clusters randomised, based on 12 trials that reported information on both.

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Table 3: Pilot trial objectives and methods

Characteristic	Number of trials (%)
Primary objective is feasibility [1]	10 (56)
Main feasibility objective given	
Where feasibility is primary objective	
Implementing intervention	6/10 (60)
Recruitment and retention	3/10 (30)
Feasibility of cluster design	1/10 (10)
Where feasibility is not primary objective [2]	
Implementing intervention	3/8 (38)
Recruitment	2/8 (25)
Cluster design	1/8 (13)
Feasibility of trial being able to answer the effectiveness question (and what study design would enable this)	1/8 (13)
Feasibility of larger study	1/8 (13)
Method used to address main feasibility objective given	
Where feasibility is primary objective	
Descriptive statistics and/or qualitative	9/10 (90)
Statistical test	1/10 (10)
Where feasibility is not primary objective	
Descriptive statistics/Qualitative	3/8 (38)
None given/reported elsewhere	5/8 (63)
Rationale for numbers in pilot trial based on formal power calculation for effectiveness/ efficacy [3]	0/8 (0)
Performing any formal hypothesis testing for effectiveness/ efficacy	9/18 (50)
Making any statements about effectiveness/ efficacy without a caveat	4/18 (22)

[1] Where the primary objective was not feasibility, the primary objective was effectiveness/ potential effectiveness and was addressed using statistical tests.
[2] One of the inclusion criteria was that studies were assessing feasibility, but it did not have to be the primary objective
[3] Based on 8 trials that reported a rationale for the sample size of the pilot trial

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Table 4: Number (%) of reports adhering to pilot CRT quality criteria

	Item	Criterion	n(%)
Title and Abstract	1a	Term 'pilot' or 'feasibility' included in the title Identification as a pilot or feasibility randomised trial in the title	15 (83) 12 (67)
	1a	***Term 'cluster' included in the title*** ***Identification as a cluster randomised trial in the title***	12 (67) 12 (67)
Introduction	2a [S]	Scientific background and explanation of rationale for future definitive trial reported Reasons for randomised pilot trial reported	18 (100) 7 (39)
	2a	***Rationale given for using cluster design***	6 (33)
Methods – Trial design	3a	Description of pilot trial design	18 (100)
	3a	***Definition of cluster***	18 (100)
	3b	Reported any changes to methods after pilot trial commencement If yes, reported reasons	5 (28) 5/5 (100)
Methods – Participants	4a	Reported eligibility criteria for participants	13 (72)
	4a	***Reported eligibility criteria for clusters***	9 (50)
	4b	Reported settings and locations where the data were collected	18 (100)
	4c [N]	Reported how participants were identified ***Reported how clusters were identified*** Reported how participants were consented [1] ***Reported how clusters were consented***	9 (50) 6 (33) 13/17 (76) 2 (11)
Methods – Interventions	5	Described the interventions for each group	13 (72)
Methods - Outcomes	6b	Reported any changes to pilot trial assessments or measurements after pilot trial commencement If yes, reported reasons	1 (6) 1/1(100)
	6c [N]	Reported criteria used to judge whether, or how, to proceed with the future definitive trial	3 (17)
Methods – Sample size	7a [S]	Reported a rationale for the sample size of the pilot trial	8 (44)
	7a	***Cluster design considered during the description of the rationale for numbers in the pilot trial***	3 (17)
	7b	Reported stopping guidelines	0 (0)
Methods - Randomisation	8a	Reported method used to generate the random allocation sequence	9 (50)
	8b	Reported randomisation method	13 (72)
	9	Reported mechanism used to implement the random allocation sequence Reported allocation concealment	4 (22) 7 (39)
	10/ ***10a***	Reported who: Generated the random allocation sequence ***Enrolled clusters*** ***Assigned clusters to interventions***	 8 (44) 3 (17) 4 (22)
	10c	***Reported from whom consent was sought*** *Reported whether consent was sought from participants* ***Reported whether consent was sought from clusters*** ***Reported whether participant consent was sought before or after randomisation*** [1]	2 (11) 17 (94) 2 (11) 8/17 (47)
Methods - Blinding	11a	Reported on whether there was blinding Reported who was blinded [2] Reported how they were blinded [2]	10 (56) 6/14 (43) 1/14 (7)
Methods – Analytical methods	***12a***	***Reports clustering accounted for in any of the methods used to address pilot trial objectives/ research questions*** [3]	13/17 (76)
Results – Participant flow	13*	Reports a diagram with flow of individuals through the trial	12 (67)
	13***	***Reports a diagram with flow of clusters through the trial***	10 (56)
	13a/ ***13a*** [S]	Reported number of: Individuals ***(Clusters)*** approached and/or assessed for eligibility [4] Individuals ***(Clusters)*** randomly assigned [4] Individuals ***(Clusters)*** that received intended treatment [4; 4] Individuals ***(Clusters)*** that were assessed for primary objective [4; 4]	 8/17 (47); 10/18 (56) 13/17 (76); 17/18 (94) 8/17 (47); 5/17 (29) 16/17 (94); 14/17 (82)
	13b/ ***13b***	Reported number of: Losses for individuals ***(Clusters)*** after randomisation [4*; 4] Exclusions for individuals ***(Clusters)*** after randomisation [4; 4]	 11/16 (69); 6/17 (35) 1/17 (6); 3/17 (18)
	14a	Reported on dates defining the periods of recruitment	8 (44)

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		Reported on dates defining the periods of follow up	11 (61)
	14b	Reported the pilot trial ended/stopped	0 (0)
Results – Baseline data	15	Reported a table showing baseline characteristics for the individual level If yes, by group	12 (67) 11/12 (92)
	15	***Reported a table showing baseline characteristics for the cluster level*** ***If yes, by group***	2 (11) 2/2 (100)
Results – Outcomes and estimation	17a	Reported results for main feasibility objective (quantitative or qualitative) [5]	13/17 (76)
Results - Harms	19	Reported on harms or unintended effects	4 (22)
	19a [N]	Reported other unintended consequences	0 (0)
Discussion	20 [S]	Reported limitations of pilot trial Reported sources of potential bias Reported remaining uncertainty	17 (94) 10 (56) 10 (56)
	21 [S]	Reported generalisability of pilot trial methods/findings to future definitive trial or other studies	16 (89)
	22	Interpretation of feasibility consistent with main feasibility objectives and findings [5]	12/17 (71)
	22A [N]	Reported implications for progression from the pilot to the future definitive trial	16 (89)
Other information	23	Reported registration number for pilot trial Reported name of registry for pilot trial	11 (61) 11 (61)
	24 [S]	Reported where the pilot trial protocol can be accessed	7 (39)
	25	Reported source of funding	18 (100)
	26 [N]	Reported ethical approval/research review committee approval If yes, reported reference number	17 (94) 8/17 (47)

Item numbers in normal font refer to the item in the CONSORT extension for pilot trials that the quality assessment item is based on.

Item numbers in bold italics refer to the item in the CONSORT extension for CRTs that the quality assessment item is based on.

[N] represents new items in the CONSORT extension for pilot trials compared to the CONSORT 2010 for RCTs.

[S] represents items in the CONSORT extension for pilot trials that are substantially adapted from the CONSORT 2010 for RCTs.

*The CONSORT statements do not include an item 13 but there is a participant flow subheading which strongly recommends a diagram. We therefore reference this subheading as 'item 13' here.

[1] Item not relevant for 1 trial [A12] because they said that the Ethics Board determined it could be conducted without informed consent from patients or surrogates.

[2] Item not relevant for 4 trials [A7, A10, A12, A18] because they reported that blinding was not used.

[3] Item not relevant for 1 trial because no confidence intervals/p-values were given,[A17] so clustering did not need to be accounted for in any of their methods because effect estimates are not biased by cluster randomisation, only confidence intervals/p-values.

[4] Not relevant for 1 trial due to the design of the study.[A10] (This paper was different from the others such that it was not relevant to extract these items. The clusters were postcode areas and they were assessing two online recruitment interventions and comparing the success of the recruitment interventions. As such, participants were those who completed the online questions, and each arm of the study had a "total population ranging from 1.6 to 2 million people clustered in 4 postcode areas")

[4*] Not relevant for 2 trials due to the design of these studies.[A10, A12] (See reason above for A10. For A12, data was collected from medical patient charts so these items were not relevant to extract)

[5] One paper reports the feasibility results in a separate paper so is not included.[A3]

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Table 5: Number (%) of quality assessment criteria reported by each pilot CRT in this review

Study	Overall n(%)*	Title & abstract and Introduction n(%)	Methods n(%)	Results n(%)	Discussion and Other information n(%)
Drahota [A7]	50(70)	6(86)	17(59)	18(78)	9(75)
Pai [A12]	48(69)	5(71)	17(61)	18(78)	8(67)
Mytton [A17]	50(68)	4(57)	21(66)	13(57)	12(100)
Thomas [A18]	46(67)	5(71)	17(59)	15(65)	9(90)
Teut [A14]	49(66)	6(86)	20(63)	14(61)	9(75)
Taylor [A6]	47(64)	7(100)	16(52)	13(57)	11(92)
Légaré [A3]	42(58)	3(43)	18(56)	14(61)	7(64)
Begh [A1]	41(56)	5(71)	16(52)	11(48)	9(75)
Jago [A15]	39(55)	4(57)	11(38)	13(57)	11(92)
Jones [A10]	32(52)	7(100)	10(33)	6(50)	9(75)
Moore [A11]	37(52)	5(71)	13(45)	8(35)	11(92)
Michie [A16]	36(51)	3(43)	15(52)	8(36)	10(83)
Jones [A2]	37(51)	3(43)	15(48)	10(45)	9(75)
Jago [A5]	33(46)	4(57)	13(45)	10(43)	6(50)
Gifford [A9]	33(45)	6(86)	12(39)	8(35)	7(58)
Reeves [A13]	29(41)	6(86)	11(38)	7(32)	5(42)
Frenn [A8]	18(26)	1(14)	5(17)	7(32)	5(42)
Hopkins [A4]	16(23)	2(29)	4(14)	4(18)	6(50)

*This is the overall number(percentage) of the quality assessment items in Table 4 that are reported by each study. The other columns look at this within categories. Note that the denominator varies between studies because not all quality assessment items are relevant for all studies (see footnote of Table 4) and not applicable for some items if a related item is not reported (see items 3b, 6b, 15, 26 in Table 4).

FIGURES

Figure 1: Flow diagram of the identification process for the sample of 18 pilot cluster randomised trials included in this review

APPENDICES

Appendix 1: Search strategy

Appendix 2: Data extracted

Appendix 3: List of studies included in this systematic review

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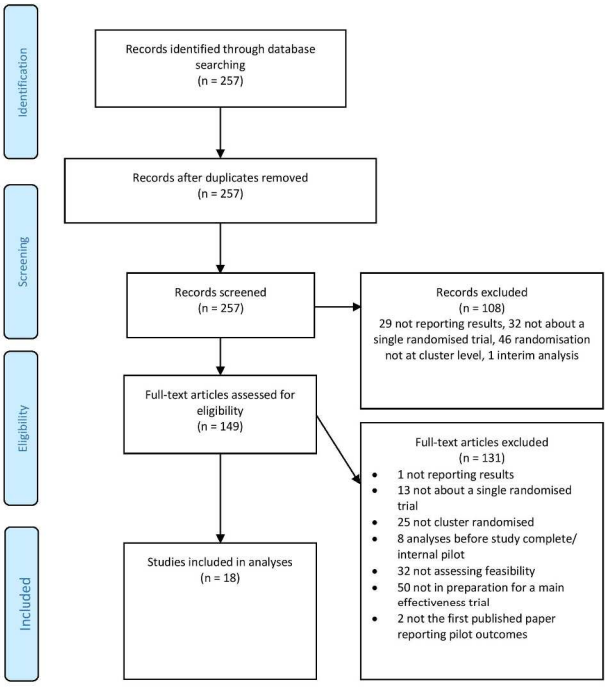

Flow diagram of the identification process for the sample of 18 pilot cluster randomised trials included in this review

210x297mm (300 x 300 DPI)

Appendix 1: Search strategy

#1:	randomised trial [All fields]
#2:	randomized trial [All fields]
#3:	#1 OR #2
#4:	clinical trial [All Fields]
#5:	#3 AND #4
#6:	((cluster randomization) OR (cluster randomisation) OR (cluster) OR (clustered) OR (clustering) OR (clusters) OR (group-randomized) OR (group-randomised) OR (randomisation unit) OR (randomization unit)) [All fields]
#7:	#5 AND #6
#8:	pilot [Title/Abstract]
#9:	feasibility [Title/Abstract]
#10:	#8 OR #9
#11:	#7 AND #10
#12:	protocol [Title]
#13:	#11 NOT #12
#14:	("2011/01/01"[Date - Publication] : "2014/12/31"[Date - Publication])
#15:	#13 AND #14

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Appendix 2: Data extracted

Items	Data extracted	Further information
Descriptives		
Name of first author	Text	
Publication year	Date	The earlier of the print date and electronic date
Journal	Text	
Title	Text	
Country (or countries) in which the trial was set	Text	
Setting where the data were collected	Text	e.g. community, hospital clinic etc.
Pilot trial design	Parallel CRT, factorial CRT, cross-over CRT, other CRT	
What was the cluster?	Text	
Method of cluster randomisation	Text	
Number of clusters randomised	Number	
Number of individuals randomised	Number	
Additional items relating to pilot trial methodology		
Primary objective/ research question of the pilot trial	Text	As specified by the author, else the outcome used in the sample size justification, or else the first objective/ research question mentioned in the abstract or else main text (following a similar method as that used by Diaz-Ordaz et al.[8])
Is the primary objective feasibility?	Yes/No	
Primary objective/ research question measure	Text	
Method used to address primary objective/ research question	Text	Defined as the main method presented for the primary objective/ research question
Main feasibility objective/ research question of the pilot trial	Text	As specified by the author, else the feasibility outcome used in the sample size justification, or else the first feasibility objective/ research question mentioned in the abstract or else main text
Main feasibility objective/ research question measure	Text	
Method used to address main feasibility objective/ research question	Text	Defined as the main method presented for the primary objective/ research question
Is the rationale for numbers in the pilot trial based on formal power calculation for effectiveness (efficacy)?	Yes/no	
Is the paper performing any formal hypothesis testing for effectiveness/ efficacy?	Yes/no	
Is the paper making any statements about effectiveness/ efficacy without a caveat	Yes/no	The caveat must explain that it is an indication of *potential* effectiveness or explain that the study is underpowered
Title and Abstract		
Term 'pilot' or 'feasibility' included in the title	Yes/no	
Identification as a pilot or feasibility randomised trial in the title	Yes/no	Require 'pilot randomised trial' or 'feasibility randomised trial' in the title, or 'pilot study' or 'feasibility study' and 'randomised trial' in the title
Term 'cluster' included in the title	Yes/no	
Identification as a cluster randomised trial in the title	Yes/no	Require 'cluster randomised trial' in the title – don't accept 'clustered' as this can imply correlation rather than cluster randomised
Introduction		
Scientific background and explanation of rationale for future definitive trial reported	Yes/no	
Reasons for randomised pilot trial reported	Yes/no	We specified there needed to be a rationale in the introduction section for the randomised pilot trial, which was not just simply stating the aims/ objectives/outcomes of the pilot trial but gave a clear rationale of why the pilot trial was needed before proceeding to the future definitive trial.

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Rationale given for using cluster design	Yes/no	
Methods – Trial design		
Description of pilot trial design	Yes/no	
Definition of cluster	Yes/no	
Reported any changes to methods after pilot trial commencement If yes, reported reasons	Yes/no Yes/no	
Methods – Participants		
Reported eligibility criteria for participants	Yes/no	
Reported eligibility criteria for clusters	Yes/no	
Reported settings and locations where the data were collected	Yes/no	
Reported how participants were identified	Yes/no	We required that the authors describe the exact way the participants were identified (e.g. during consultations/visits to the cluster, or through advertisement requesting volunteers)
Reported how clusters were identified	Yes/no	We required that the authors describe the exact way the clusters were identified (e.g. all clusters in a particular geographical location, or selection from a register/list etc.)
Reported how participants were consented	Yes/no	
Reported how clusters were consented	Yes/no	
Methods – Interventions		
Described the interventions for each group	Yes/no	
Methods – Outcomes		
Reported any changes to pilot trial assessments or measurements after pilot trial commencement If yes, reported reasons	Yes/no Yes/no	
Reported criteria used to judge whether, or how, to proceed with the future definitive trial	Yes/no	
Methods – Sample size		
Reported a rationale for the sample size of the pilot trial	Yes/no	
Cluster design considered during the description of the rationale for numbers in the pilot trial	Yes/no	We required that the authors show some consideration about clustering during the description of their sample size calculation, even if not formally accounting for it currently but describe during their rationale that they e.g. plan to estimate the design effect in the future definitive trial
Reported stopping guidelines	Yes/no	
Methods – Randomisation		
Reported method used to generate the random allocation sequence	Yes/no	e.g. random numbers table, coin tossing, computer generated random list
Reported randomisation method If yes, randomisation method	Yes/no Text	 e.g. simple, stratification, blocking, matching
Reported mechanism used to implement the random allocation sequence	Yes/no	e.g. sequentially numbered containers, sealed envelopes, central telephone
Reported allocation concealment	Yes/no	
Reported who: Generated the random allocation sequence Enrolled clusters Assigned clusters to interventions	 Yes/no Yes/no Yes/no	 Tick yes for last two points if a 'who' is not relevant since done by e.g. post/online
Reported whether consent was sought from participants	Yes/no	
Reported whether consent was sought from clusters	Yes/no	
Reported from whom consent was sought	Yes/no	I.e. reported both whether consent was sought from participants and whether consent was sought from clusters
Reported whether participant consent was sought before or after randomisation	Yes/no	
Methods – Blinding		
Reported on whether there was blinding	Yes/no	

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Reported who was blinded	Yes/no	tick yes if they report anyone who was blinded, even if they don't report on everyone
Reported how they were blinded	Yes/no	tick yes if they report on how anyone was blinded, even if they don't report on how everyone who was blinded was blinded
Methods – Analytical methods		
Reports clustering accounted for in any of the methods used to address pilot trial objectives/ research questions	Yes/no	
Results – Participant flow		
Reports a diagram with flow of individuals through the trial	Yes/no	
Reports a diagram with flow of clusters through the trial	Yes/no	
Reported number of: Individuals approached and/or assessed for eligibility Individuals randomly assigned Individuals that received intended treatment Losses for individuals after randomisation Exclusions for individuals after randomisation Individuals that were assessed for primary objective	 Yes/no Yes/no Yes/no Yes/no Yes/no Yes/no	
Reported number of: Clusters approached and/or assessed for eligibility Clusters randomly assigned Clusters that received intended treatment Losses for clusters after randomisation Exclusions for clusters after randomisation Clusters that were assessed for primary objective	 Yes/no Yes/no Yes/no Yes/no Yes/no Yes/no	
Results – Recruitment		
Reported on dates defining the periods of recruitment	Yes/no	
Reported on dates defining the periods of follow up	Yes/no	
Reported the pilot trial ended/stopped	Yes/no	
Results – Baseline data		
Reported a table showing baseline characteristics for the individual level If yes, by group	Yes/no Yes/no	
Reported a table showing baseline characteristics for the cluster level If yes, by group	Yes/no Yes/no	
Results – Outcomes and estimation		
Reported results for main feasibility objective (quantitative or qualitative)	Yes/no	
Results – Harms		
Reported on harms or unintended effects	Yes/no	Tick yes even if reported that there were no harms
Reported other unintended consequences	Yes/no	An unintended consequence would be an unexpected result/finding that was not one of the objectives to explore and where the result would have consequences on the future definitive trial, such as a change in design/population etc.
Discussion		
Reported limitations of pilot trial	Yes/no	
Reported sources of potential bias	Yes/no	
Reported remaining uncertainty	Yes/no	
Reported generalisability of pilot trial methods/findings to future definitive trial or other studies	Yes/no	To be reporting on the generalisability of the pilot trial methods/findings to the future definitive trial, we deemed it sufficient for the paper to be discussing whether the methods/findings of the pilot study can be applied to the future definitive trial. To be reporting on the generalisability of the pilot trial methods/findings to other future trials, we deemed it sufficient for the paper to be discussing whether the methods/findings of the pilot study can be applied to other future trials.
Interpretation of feasibility consistent with main feasibility objectives and findings	Yes/no	

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Reported implications for progression from the pilot to the future definitive trial If yes, what were the implications?	Yes/no Proceed/ proceed with changes/ Further research or piloting needed first/ Don't go ahead	
Other information		
Reported registration number for pilot trial	Yes/no	
Reported name of registry for pilot trial	Yes/no	
Reported where the pilot trial protocol can be accessed	Yes/no	
Reported source of funding	Yes/no	
Reported ethical approval/research review committee approval If yes, reported reference number	Yes/no Yes/no	

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Appendix 3: List of studies included in this systematic review

(Note that the publication years given in the list below are the print publication years, rather than the earlier of the print or electronic publication year, so there is some discrepancy between the list below and Table 1)

1. Begh RA, Aveyard P, Upton P, Bhopal RS, White M, Amos A, et al. Promoting smoking cessation in Pakistani and Bangladeshi men in the UK: pilot cluster randomised controlled trial of trained community outreach workers. Trials. 2011;12:197.
2. Jones RA, Riethmuller A, Hesketh K, Trezise J, Batterham M, Okely AD. Promoting fundamental movement skill development and physical activity in early childhood settings: a cluster randomized controlled trial. Pediatr Exerc Sci. 2011;23(4):600-15.
3. Legare F, Labrecque M, LeBlanc A, Njoya M, Laurier C, Cote L, et al. Training family physicians in shared decision making for the use of antibiotics for acute respiratory infections: a pilot clustered randomized controlled trial. Health Expect. 2011;14 Suppl 1:96-110.
4. Hopkins JM, Glenn BA, Cole BL, McCarthy W, Yancey A. Implementing organizational physical activity and healthy eating strategies on paid time: process evaluation of the UCLA WORKING pilot study. Health Educ Res. 2012;27(3):385-98.
5. Jago R, Sebire SJ, Cooper AR, Haase AM, Powell J, Davis L, et al. Bristol girls dance project feasibility trial: outcome and process evaluation results. Int J Behav Nutr Phys Act. 2012;9:83.
6. Taylor WJ, Brown M, William L, McPherson KM, Reed K, Dean SG, et al. A pilot cluster randomized controlled trial of structured goal-setting following stroke. Clin Rehabil. 2012;26(4):327-38.
7. Drahota AK, Ward D, Udell JE, Soilemezi D, Ogollah R, Higgins B, et al. Pilot cluster randomised controlled trial of flooring to reduce injuries from falls in wards for older people. Age Ageing. 2013;42(5):633-40.
8. Frenn M, Pruszynski JE, Felzer H, Zhang J. Authoritative feeding behaviors to reduce child BMI through online interventions. J Spec Pediatr Nurs. 2013;18(1):65-77.
9. Gifford WA, Davies BL, Graham ID, Tourangeau A, Woodend AK, Lefebre N. Developing leadership capacity for guideline use: a pilot cluster randomized control trial. Worldviews Evid Based Nurs. 2013;10(1):51-65.
10. Jones RB, Goldsmith L, Hewson P, Williams CJ. Recruitment to online therapies for depression: pilot cluster randomized controlled trial. J Med Internet Res. 2013;15(3):e45.
11. Moore GF, Williams A, Moore L, Murphy S. An exploratory cluster randomised trial of a university halls of residence based social norms marketing campaign to reduce alcohol consumption among 1st year students. Subst Abuse Treat Prev Policy. 2013;8:15.
12. Pai M, Lloyd NS, Cheng J, Thabane L, Spencer FA, Cook DJ, et al. Strategies to enhance venous thromboprophylaxis in hospitalized medical patients (SENTRY): a pilot cluster randomized trial. Implement Sci. 2013;8:1.
13. Reeves R, West E, Barron D. Facilitated patient experience feedback can improve nursing care: a pilot study for a phase III cluster randomised controlled trial. BMC Health Serv Res. 2013;13:259.
14. Teut M, Schnabel K, Baur R, Kerckhoff A, Reese F, Pilgram N, et al. Effects and feasibility of an Integrative Medicine program for geriatric patients-a cluster-randomized pilot study. Clin Interv Aging. 2013;8:953-61.
15. Jago R, Sebire SJ, Davies B, Wood L, Edwards MJ, Banfield K, et al. Randomised feasibility trial of a teaching assistant led extracurricular physical activity intervention for 9 to 11 year olds: Action 3:30. Int J Behav Nutr Phys Act. 2014;11:114.
16. Michie L, Cameron ST, Glasier A, Larke N, Muir A, Lorimer A. Pharmacy-based interventions for initiating effective contraception following the use of emergency contraception: a pilot study. Contraception. 2014;90(4):447-53.

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17. Mytton J, Ingram J, Manns S, Stevens T, Mulvaney C, Blair P, et al. The feasibility of using a parenting programme for the prevention of unintentional home injuries in the under-fives: a cluster randomised controlled trial. Health Technol Assess. 2014;18(3):1-184.
18. Thomas LH, Watkins CL, Sutton CJ, Forshaw D, Leathley MJ, French B, et al. Identifying continence options after stroke (ICONS): a cluster randomised controlled feasibility trial. Trials. 2014;15:509.

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PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	1, 2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	3
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	3
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	5
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	3, 4
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	4
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Appendix 1
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	4
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	5, 6
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	Appendix 2
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	N/A – review of reporting quality
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	N/A –

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PRISMA 2009 Checklist

			review of reporting quality
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	N/A – review of reporting quality

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	N/A – review of reporting quality
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	N/A – review of reporting quality
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	6, 7, Figure 1
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	7, Table 1, Appendix 3
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	N/A – review of reporting quality
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	N/A – review of reporting

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PRISMA 2009 Checklist

			quality
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	N/A – review of reporting quality
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	N/A – review of reporting quality
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	N/A – review of reporting quality
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	9, 10, 11
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	12
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	11
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	13

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

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The Quality of Reporting of Pilot and Feasibility Cluster Randomised Trials: A Systematic Review

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The Quality of Reporting of Pilot and Feasibility Cluster Randomised Trials: A Systematic Review

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ABSTRACT

Objectives: To systematically review the quality of reporting of pilot and feasibility CRTs. In particular, to assess (1) the number of pilot CRTs conducted between 01/01/2011 and 31/12/2014, (2) whether objectives and methods are appropriate and (3) reporting quality.

Methods: We searched PubMed (2011-2014) for CRTs with 'pilot' or 'feasibility' in the title or abstract; that were assessing some element of feasibility; and showing evidence the study was in preparation for a main effectiveness/efficacy trial. Quality assessment criteria were based on the Consolidated Standards of Reporting Trials (CONSORT) extensions for pilot trials and CRTs.

Results: Eighteen pilot CRTs were identified. Forty-four percent did not have feasibility as their primary objective, and many (50%) performed formal hypothesis testing for effectiveness/efficacy despite being underpowered. Most (83%) included 'pilot' or 'feasibility' in the title, and discussed implications for progression from the pilot to the future definitive trial (89%), but fewer reported reasons for the randomised pilot trial (39%), sample size rationale (44%), or progression criteria (17%). Most defined the cluster (100%), and number of clusters randomised (94%), but few reported how the cluster design affected sample size (17%), whether consent was sought from clusters (11%), or who enrolled clusters (17%).

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Conclusions: That only 18 pilot CRTs were identified necessitates increased awareness of the importance of conducting and publishing pilot CRTs and improved reporting. Pilot CRTs should primarily be assessing feasibility, avoiding formal hypothesis testing for effectiveness/efficacy, and reporting reasons for the pilot, sample size rationale, and progression criteria, as well as enrolment of clusters, and how the cluster design affects design aspects. We recommend adherence to the CONSORT extensions for pilot trials and CRTs.

Article summary

Strengths and limitations of this study

- We used a robust search and data extraction procedure, including validation of the screening/sifting process and double data extraction.
- We may have missed some studies, since our criteria excluded studies not including 'pilot' or 'feasibility' in the title or abstract, and those not clearly in preparation for a main trial.

BACKGROUND

In a cluster randomised trial (CRT) clusters, rather than individuals, are the units of randomisation. A cluster is a group (usually predefined) of one or more individuals. For example, clusters could be hospitals and the individuals, the patients within those hospitals. CRTs are often chosen for logistical reasons, prevention of contamination across individuals, or because the intervention is targeted at the cluster level. CRTs are useful for evaluating complex interventions. However, they have added complexity in terms of design, implementation, and analysis and so it is important to ensure that carrying out a CRT is feasible before conducting the future definitive trial.[1]

A feasibility study conducted in advance of a future definitive trial is a study designed to answer the question about whether the study can be done and whether one should proceed with it. A pilot study answers the same question but in such a study part or all of the future trial is carried out on a smaller scale.[2] Thus all pilot studies are also feasibility studies. Pilot studies can be randomised or non-randomised; for brevity we use the term pilot CRT throughout this paper to refer to a randomised study with a clustered design that is in preparation for a future definitive trial assessing effectiveness/efficacy.[3, 4] The focus of pilot trials is on investigating areas of uncertainty about the

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future definitive trial to see whether it is feasible to carry out, so the data, methods, and analysis are different from an effectiveness/efficacy trial. In particular, more data might be collected on items such as recruitment and retention to assess feasibility, methods may include specifying criteria to judge whether to proceed with the future definitive trial, and analysis is likely to be based on descriptive statistics since the study is not powered for formal hypothesis testing for effectiveness/efficacy.

Arnold et al. highlight the importance of pilot studies being of high quality.[5] Good reporting quality is essential to show how the pilot has informed the future definitive trial as well as to allow readers to use the results in preparing for similar future trials. The number of pilot and feasibility studies in the literature is increasing. However, Arain et al. indicate that reporting of pilot studies is poor.[6] There are no previous reviews of the reporting quality of pilot CRTs, despite the extra complications arising from the clustered structure. The aim of this review is to reveal the quality of reporting of pilot CRTs published between 01/01/2011 and 31/12/2014. We extracted information to describe the sample of pilot CRTS and to assess quality, with quality criteria based on the Consolidated Standards of Reporting Trials (CONSORT) extension for CRTs,[7] and a CONSORT extension for pilot trials which SE and CC were involved in the final stages of development of during this review.[3, 4] We present recommendations for improving the conduct, analysis and reporting of these studies and expect this to improve the quality, usefulness and interpretation of pilot CRTs in the future. We know current reporting of CRTs is suboptimal,[8-11] and thus we expected the reporting of pilot CRTs to be even poorer.

The questions addressed by this review are:

1) How many pilot CRTs have been conducted between 01/01/2011 and 31/12/2014?
2) Are pilot CRTs using appropriate objectives and methods?
3) To what extent is the quality of reporting of pilot CRTs sufficient?

METHODS

Inclusion and exclusion criteria

We included papers published in English with a publication date (print or electronic) between 01/01/2011 and 31/12/2014. We chose the start date to be after the updated CONSORT 2010 was published.[12] We estimated a search covering four years would give us a reasonable number of papers to perform our quality assessment, and that later papers would be similar in terms of quality

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of reporting since the CONSORT for pilot trials was not published until the end of 2016. The study had to be a CRT, have the word 'pilot' or 'feasibility' in the title or abstract, be assessing some element of feasibility, and show evidence that the study was in preparation for a specific trial assessing effectiveness/efficacy that is planned to go ahead if the pilot trial suggests it is feasible (i.e. not just a general assessment of feasibility issues to help researchers in general, although pilot trials may do this as an addition). Regardless of how authors described a study, we did not consider it to be a pilot trial if it was *only* looking at effectiveness/efficacy because we wanted to exclude those studies that claim to be a pilot/feasibility trial simply as justification for small sample size.[13] The paper had to be reporting results (i.e. not a protocol or statistical analysis plan) and had to be the first published paper reporting pilot outcomes (i.e. not an extension/follow-up study for a pilot study already reported, and not a second paper reporting further pilot outcomes). Interim analyses, analyses before the study was complete, and internal pilots were excluded; the CONSORT extension for pilot trials on which we based the quality assessment does not apply to internal pilots.[3, 4] No studies were excluded on the basis of quality since the aim was to assess the quality of reporting.

Data sources and search methods

We searched PubMed for relevant papers in September 2015. We searched for the words 'pilot' or 'feasibility' in the title or abstract, a search strategy similar to that used by Lancaster et al. [14] We combined this with a search strategy to identify CRTs; this was similar to the strategy used by Diaz-Ordaz et al. [8] The full electronic search strategy is given in Appendix 1.

Sifting and validation

The titles and abstracts of all papers identified by the electronic search were screened by CC for possible inclusion. Full texts were obtained for those papers identified as definitely or possibly satisfying the inclusion criteria and sifted by CC for inclusion. As validation, CL carried out the same screening and sifting process independently on a 10% random sample of electronically identified papers. For full texts where there was uncertainty whether the paper should be included, it was referred to SE for a final decision.

Refining the inclusion process

We refined the screening and sifting process following piloting. In particular we rejected a more restrictive PubMed search that required 'pilot' or 'feasibility' in the title rather than allowing these words to occur in the title *or* abstract because this missed relevant papers; we altered the order of the exclusion criteria to make the process more streamline; and we relaxed one inclusion criteria,

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requiring evidence that the pilot trial was in preparation for a future definitive trial rather than an explicit statement that authors were planning a future definitive trial. The protocol was updated, and is available from the corresponding author.

Data Extraction

CC and CL independently extracted data from all papers selected for inclusion in the review, and followed rules on what to extract (see Further information column of Appendix 2). Extracted data were recorded in an Excel spreadsheet. Discrepancies were resolved by discussion between CC and CL, and where agreement could not be reached a final decision was made by SE.

For each pilot CRT included in the review, we extracted information to describe the trials, including publication date (print date unless there was an earlier electronic date), country in which the trial was set, number of clusters randomised, method of cluster randomisation and, following the CONSORT extension for pilot trials' recommendation to focus on objectives rather than outcomes, the primary objective. We defined the primary objective using method similar to that used by Diaz-Ordaz *et al*.[8] for primary outcomes i.e. as that specified by the author, else the objective used in the sample size justification, or else the first objective mentioned in the abstract or else main text.

To assess whether the pilot trials were using appropriate objectives and methods, we collected information on whether the primary objective was about feasibility, the method used to address the main feasibility objective, the rationale for numbers in the pilot trial, and whether there was formal hypothesis testing for, or statements about, effectiveness/efficacy without a caveat about the small sample size.

To assess reporting quality, we created a list of quality assessment items based on the CONSORT extension for pilot trials.[3, 4] We also looked at the CONSORT extension for CRTs,[7] and incorporated any cluster-specific items into our quality assessment items. Where a CRT item became less relevant in the context of a pilot trial, we did not extract it (e.g. whether variation in cluster sizes was formally considered in the sample size calculation). In addition, where there was a substantial difference between the item for the CONSORT extension for CRTs and that for the pilot trial extension and the items were not compatible, we used the latter item (e.g. focusing on objectives rather than outcomes). We recognised the need to balance comprehensiveness and feasibility.[11] Therefore, where items referred to objectives or methods, we extracted this for the primary objective only. We also did not extract on whether papers reported a structured summary of trial

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design, methods, results, and conclusions. The final version of the full list of data extracted, and further information on each item extracted, is included in Appendix 2.

Refining data extraction

Initially CC extracted data on a random 10% sample of papers. However, some of the items were difficult to extract in a clear, standardised way, as similarly noted by Ivers et al,[11] so these items were removed. In particular: whether the objectives, intervention, or allocation concealment were at the individual level, cluster level, or both; and other analyses performed or other unintended consequences (difficult to decipher from papers whether it classified as an 'other'). Furthermore, some items were deemed easier to extract if split into two items, for example; 'reported why the pilot trial ended/stopped' which we subsequently split into 'reported the pilot trial ended/stopped' and 'if so, what was the reason'.

Analysis

Data were analysed using Excel version 2013. We describe the characteristics of the pilot CRTs using descriptive statistics. Where we extracted text, we established categories during analysis by grouping similar data, for example grouping the different primary objectives. To assess adherence to the CONSORT checklists, we present the number and percentage reporting each item. This report adheres, where appropriate, to the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) statement.[15]

Patient involvement

No patients were involved in the development of the research question, design or conduct of the study, interpretation or reporting. No patients were recruited for this study. There are no plans to disseminate results of the research to study participants.

RESULTS

The electronic PubMed search identified 257 published papers. We rejected 108 during screening (29 not reporting results; 32 not about a single randomised trial; 46 not cluster randomised; 1 interim analysis). The remaining 149 full-text articles were assessed for eligibility, and 131 more papers were rejected (1 not reporting results; 13 not about a single randomised trial; 25 not cluster

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randomised; 8 analyses before study complete/internal pilot; 32 not assessing feasibility; 50 not in preparation for a future definitive effectiveness/efficacy trial; 2 not the first published paper reporting pilot outcomes). This left 18 studies to be included in the analysis.[A1-A18]. The full list of studies is included in Table 1, with citations in Appendix 3. Figure 1 shows the flow diagram of the identification process for the sample of 18 pilot CRTs.

There was 96% agreement between CC and CL for the 10% random sample used for the screening and sifting validation (based on 26 papers), with a kappa coefficient of 0.84.

Trial characteristics

In general, the more recent the publication date, the more pilot CRTs were identified, but with the most identified in 2013 (Table 2). Of the 18 included studies, the majority (56%) were set in the UK. All other countries were represented only once except for Canada (3 trials) and USA (2 trials). Of those reporting the method of randomisation, the majority (69%) used stratified with blocked randomisation. The median number of clusters randomised was 8 (IQR: 4 to 16) with a range from 2 to 50.

Pilot trial objectives and methods

Ten (56%) of the 18 included pilot trials had feasibility as their primary objective, for example assessing feasibility of implementing the intervention (6 trials), of recruitment and retention (3 trials), and of the cluster design (1 trial) (Table 3). All ten trials reported a corresponding measure to assess the feasibility objective; most (90%) used descriptive statistics and/or qualitative methods to address the objective. In one trial a statistical test was used to address their primary feasibility objective without the authors designing the study to be adequately powered to do so.

The remaining eight trials had an effectiveness/efficacy primary objective, and used statistical tests to address this. Nevertheless these eight trials all had feasibility as one of their other objectives (this was an inclusion criterion). The feasibility objectives were similar to those where the feasibility was primary, but expressed more generally in two trials, for example, looking at the feasibility of the future definitive trial,[A16] and looking at whether the future definitive trial could answer the effectiveness question and which study design would enable this.[A10] In only three trials was a measure to assess the feasibility objective reported, using either quantitative or qualitative measures.

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Eight trials reported a rationale for the numbers in the pilot trial, with all of these following best practice in not basing the rationale on a formal sample size calculation for effectiveness/efficacy. Nine (50%) trials performed any formal hypothesis testing for effectiveness/efficacy, regardless of whether this was for the primary or a secondary objective. Of these nine trials, four of the conclusions about effectiveness/efficacy were made without any caveats about the imprecision of estimates or possible lack of representativeness because of the small samples.

Quality of reporting – by items

The pilot CRTs in our review are published after the CONSORT 2010 for RCTs but before the CONSORT extension for pilot trials. Therefore, to present data on quality of reporting, we looked at our list of quality assessment items based on the CONSORT extension for pilot trials, and grouped reporting items into three categories (Table 4): (1) items in the CONSORT extension for pilot trials that are new compared to CONSORT 2010 for RCTs, (2) items in the CONSORT extension for pilot trials that are substantially adapted from CONSORT 2010 for RCTs and (3) items in the CONSORT extension for pilot trials that are the same as or have only minor differences from CONSORT 2010 for RCTs, plus items in the CONSORT extension for CRTs.[3, 4, 7, 12]

In the tables, denominators for proportions are based on papers for which the item is relevant. Not all items are relevant for all trials, due to their design, so we highlight where this applies in the table footnotes. The footnote of Table 4 also explains where the quality assessment items come from, with different font differentiating items based on the CONSORT extension for pilot trials and the CONSORT extension for CRTs, and a key to highlight which of the three categories above the item falls under.

New items

Five new items were added to the CONSORT extension for pilot trials on the identification and consent process, progression criteria, other unintended consequences, implications for progression, and ethical approval.[3, 4] See items with [N] in column 2 of Table 4. In our review, how participants were identified and consented was reported by 50% and 76% of the pilot CRTs, respectively, but how clusters were identified and consented was reported by just 33% and 11%, respectively. Only 3 trials (17%) reported criteria used to judge whether or how to proceed with the future definitive trial, with two giving numbers that must be exceeded such as recruitment, retention, attendance, and data collection percentages,[A17, A2] and one giving categories of “definitely feasible”,

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"possibly feasible", and "not feasible".[A12] The item on other unintended consequences was reported by none of the pilot CRTs, although it is unclear whether this is due to poor reporting or because no unintended consequences occurred. Implications for progression from pilot to future definitive trial was reported by 16 trials (89%), with nine reporting to proceed/proceed with changes, five reporting further research or piloting is needed first, and two reporting to not go ahead with the future definitive trial. 94% reported ethical approval/research review committee approval, but only 47% of them also reported the corresponding reference number.

Substantially adapted items

Six items in the CONSORT extension for pilot trials were substantially adapted from CONSORT 2010 for RCTs, regarding reasons for the randomised pilot trial, sample size rationale for the pilot trial, numbers approached and/or assessed for eligibility, remaining uncertainty about feasibility, generalisability of pilot trial methods and findings, and where the pilot trial protocol can be accessed.[3, 4] See items with [S] in column 2 of Table 4. Reasons for the randomised pilot trial were reported by 39% of the pilot CRTs. Eight trials (44%) gave a rationale for the sample size of the pilot trial. Pilot trials should always report a rationale for their sample size; this can be qualitative or quantitative, but shouldn't be based on a formal sample size calculation for effectiveness/efficacy. In this review, the rationales were based on logistics,[A15] resources,[A14] time,[A16] a balance of practicalities and need for reasonable precision,[A18] a general statement that it was considered sufficient to address the objectives of the pilot trial,[A17] formal [A6] and non-formal [A7] calculation to enable estimation of parameters in the future definitive trial, and a formal calculation based on the primary feasibility outcome.[A12] Of these rationales, good examples include "The decision to include eight apartment-sharing communities was based on practical feasibility that seemed appropriate according to funding and the personal resources available",[A14] as well as "The sample size was chosen in order to have two clusters per randomized treatment and the number of participants per cluster was based on the number of degrees of freedom needed within each cluster to have reasonable precision to estimate a variance".[A6] The number of individuals approached and/or assessed for eligibility was reported by 47%, and the number of clusters by 56%. Remaining uncertainty was reported by 56% of the pilot CRTs. 89% reported generalisability of pilot trial methods/findings to the future definitive trial or other studies, but clarity of reporting was lacking as it was difficult to distinguish between references to the future definitive trial versus other future studies due to ambiguous phrases such as "in a future trial". Only 39% reported where the pilot trial protocol could be accessed.

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Items essentially taken from CONSORT 2010 for RCTs or the CONSORT extension for CRTs

For the remaining items, reporting quality was variable. Some were reported by fewer than 20% of the pilot CRTs, for example considering the cluster design in the sample size rationale for the pilot trial (17%) (item 7a), reporting whether consent was sought from clusters (11%) and who enrolled them (17%) (items 10c and 10a), how people were blinded (7% of applicable trials) (item 11a), number of excluded individuals (6% of applicable trials) and clusters (18% of applicable trials) after randomisation (item 13b), and a table showing baseline cluster characteristics (11%) (item 15). Those reported most well, by more than 80% of the pilot CRTs, included reporting 'pilot' or 'feasibility' in the title (83%) (item 1a), scientific background and explanation of rationale for future definitive trial (100%) (item 2a), pilot trial design (100%) (item 3a), nature of the cluster (100%) (item 3a), settings and locations where the data were collected (100%) (item 4b), whether consent was sought from participants (94%) (item 10c), number of clusters randomised (94%) and assessed for primary objective (82% of applicable trials) (item 13a), number of individuals assessed for primary objective (94% of applicable trials) (item 13a), limitations of pilot trial (94%) (item 20), and source of funding (100%) (item 25).

Quality of reporting – by study

Finally, in Table 5 we present the number (percentage) of quality assessment items reported by each study. We provide an overall score, as well as a score by categories of CONSORT. The quality of reporting varies across studies, with 5 of the pilot CRTs reporting over 65% of the quality assessment items and 2 of the pilot CRTs reporting under 30%. There does not appear to be a trend of reporting quality with time. Five of the studies report 90% or more of the quality assessment items in the 'discussion and other information' category, and only two studies report less than 50%. Two of the studies report 100% of the items in the 'title and abstract and introduction' category, and five studies report less than 50%. The highest percentage of items reported by a study in the 'methods' category is 66% and the lowest is 14%. Similarly, the highest percentage of items reported by a study in the 'results' category is 78% and the lowest is 18%. Within studies, the category that is best reported tends to be the 'discussion and other information' category (had the highest percentage for 10 of the 18 pilot CRTs).

DISCUSSION

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Main findings

This is the first study to assess the reporting quality of pilot CRTs using the recently developed CONSORT checklist for pilot trials.[3, 4] Our search strategy and inclusion criteria identified 18 pilot CRTs published between 2011 and 2014. Most studies were published in the UK, perhaps driven by the availability of funding or the large number of CRTs and interest in complex interventions in the UK.

With respect to the pilot CRT objectives and methods, a considerable proportion of papers did not have feasibility as their primary objective. Of the trials reporting a sample size rationale for the pilot, all followed best practice in not carrying out a formal sample size calculation for effectiveness/efficacy, yet a substantial proportion performed formal hypothesis testing for effectiveness/efficacy. This could indicate an inappropriate attachment to hypothesis testing, although many did explain it was an indication of *potential* effectiveness or that the study was underpowered. Investigators wanting to assess effectiveness/efficacy and use statistical tests to do so should be performing a properly powered definitive trial, otherwise there is the potential for misleading conclusions affecting clinical decisions as well as misinformed decisions about the future definitive trial.[16] One may however look at *potential* effectiveness, for example using an interim or surrogate outcome, with a caveat about the lack of power.[3, 4] Moreover, one may include a progression criterion based on potential effect. If so, Eldridge and Kerry recommend any interpretation of potential effect is done by looking at the limits of the confidence interval,[13] and one should also pay attention to features of the pilot which might have biased the result (for example, convenience sampling of clusters). A positive effect finding excluding the null value would still justify the future definitive trial to estimate the effect with greater certainty, but a negative effect finding excluding the null value (i.e. strongly suggesting harm), or even a finding where the clinically important difference is excluded, might suggest not proceeding. It is good practice to pre-state such progression criteria. Finally, one may use estimates from outcome data, for example, as inputs for the sample size calculation for the future definitive trial. In particular, for pilot CRTs we may be interested in estimating the intra-cluster correlation coefficient (ICC), although we note that the ICC estimate from a pilot CRT should not be the only source for the future definitive trial sample size, because of the large amount of imprecision in a pilot trial.[17] Reporting quality of pilot CRTs was variable. Items reported well included reporting the term ‘pilot’ or ‘feasibility’ in the title, generalisability of pilot trial methods/findings to the future definitive trial or other studies, and implications for progression from the pilot to the future definitive trial, although clarity could be improved when referring to the future definitive trial rather than other future studies in general.

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Items least well reported included reasons for the randomised pilot trial, sample size rationale for the pilot trial, criteria used to judge whether or how to proceed with the future definitive trial, and where the pilot trial protocol can be accessed. These items are important so that readers can understand whether the uncertainty they are facing about their future trial has already been addressed in a pilot, researchers can make sure they have enough patients to achieve the pilot trial objectives, readers can understand the criteria for progression, and to prevent against selective reporting.

For items related to the cluster aspect of pilot CRTs, most pilot CRTs reported the nature of the cluster, and the number of clusters randomised and assessed for the primary objective. The items reported least well included considering the cluster design during the sample size rationale for the pilot trial, reporting who enrolled clusters and how they were consented, number of exclusions for clusters after randomisation, and a table showing baseline cluster characteristics. Although the number of clusters in a pilot trial is usually small it is still important to, for example, describe the cluster-level characteristics using a baseline table as it may give helpful information important for planning the future definitive trial. Moreover, while nearly all trial reports described whether consent was sought from individuals or not, seeking agreement from clusters was only described in a small minority. The items on agreement from and enrolment of clusters, baseline cluster characteristics, and number of excluded clusters are particularly important to report, since they may affect assessment of feasibility.

If we consider why some items may have been well adhered to and others not, it is interesting to observe that new items added to the CONSORT extension for pilot trials and items substantially adapted from CONSORT 2010 for RCTs were in general not well adhered to. This could perhaps be because of somewhat newer ideas that may not have been considered during design such as specifying progression criteria and considering a rationale for numbers in the pilot. Alternatively, perhaps there were aspects sometimes done but not reported due to lack of reporting guidance to remind authors; for example, the new items on how clusters were identified and consented, other unintended consequences, and ethical approval/research review committee approval reference number, and the substantially adapted items on reporting reasons for the pilot trial, number of individuals approached and/or assessed for eligibility, and where the pilot trial protocol can be accessed. With the item on unintended consequences, we recognise that investigators are free to choose what they interpret and report as an unintended consequence. We recommend careful thought that all unintended consequences that may affect the future definitive trial are reported. It

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is also interesting to observe that many of the most poorly reported items concerned methods/design (progression criteria; enrolment and consent of clusters), and in particular, justification of design aspects (reasons for randomised pilot trial; sample size rationale for pilot trial including consideration of cluster design). Within studies, the category that is worst reported is the methods, despite being crucial to allow the reader to judge the quality of the trial.

Comparison with other studies

There has not been a previous review of pilot trials using the new CONSORT extension for these trials.[3, 4] However, the review by Arain et al. looking at pilot and feasibility studies reported that 81% were performing hypothesis testing with sample sizes known to be insufficient,[6] compared to 50% of pilot CRTs in our review. Arain et al. also reported 36% of studies performing sample size calculations for the pilot. In our review, 17% performed calculations (all based on feasibility objectives), but if we include those that also correctly reported a rationale for the numbers in the pilot but without any calculation then this was 44%.

The general message that reporting of CRTs is suboptimal still holds.[8-11] The review by Diaz-Ordaz et al. (2013) of definitive trial CRTs reported that 37% presented a table showing baseline cluster characteristics, compared to 11% of pilot CRTs in our review. Diaz-Ordaz et al. (2013) also reported that 27% accounted for clustering in sample size calculations,[8] and a recent review by Fiero et al. reported 53%.[10] However, just 17% of pilot CRTs in our review considered the cluster design in the sample size rationale for the pilot trial. Both these CRT reviews reviewed effectiveness/efficacy CRTs, for which the need to take account of clustering in sample sizes is generally well understood compared to pilot trials. In pilot trials the rationale for considering the clustered design in deciding on numbers in the pilot may be different, for example, considering the number of degrees of freedom needed within each cluster to estimate a variance.[A6] In pilot trials, including a number of clusters with different characteristics may also be important to get an idea about the implementation of an intervention across different clusters.

Strengths and limitations

We used a robust search and data extraction procedure, including validation of the screening/sifting process and double data extraction. However, the use of only one database, PubMed, which is comprehensive but not exhaustive, may have missed eligible papers, and the use of conditions #3, #5, and #6 (see Appendix 1) may have been restrictive. Our aim was to get a general idea of reporting issues in the area, though, rather than doing a completely comprehensive search. Our

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inclusion criteria stipulated that papers must have the word 'pilot' or 'feasibility' in the title or abstract, so we may have missed some pilot CRTs and thus may have overestimated the percentage reporting 'pilot' or 'feasibility' in the title. This strategy may also have resulted in a skewed sample of papers with a greater tendency to adhere to CONSORT guidelines. However, our review suggests reporting of pilot CRTs need improving, so our conclusion would remain the same. We required authors to report that the trial was in preparation for a future definitive trial, so we expect that items related to the future definitive trial (e.g. progression criteria, generalisability, implications) may be better reported than they would for all publications of pilot CRTs which might include papers that did not report that they were in preparation for a future definitive trial clearly enough to be included. During sifting, we identified 32 trials that had 'pilot' or 'feasibility' in the title/abstract, but were not assessing feasibility. A third of these were identified because they referred to 'pilot' or 'feasibility' at some point in the abstract but it was not in reference to the current trial (e.g. stating feasibility has already been shown), but the other two thirds were labelled as a pilot or feasibility trial yet showed no evidence of assessing feasibility and were only assessing effectiveness. This is an important point as our review may appear to overestimate reporting quality by not including these studies. That there are underpowered main trials being published as pilot or feasibility studies is something that the academic community should look to prevent. During sifting, we also identified 50 trials that were assessing feasibility but did not show evidence of being in preparation for a future definitive trial. Most were assessing the feasibility of implementing an intervention targeted at members of the public, or discussing feasibility of the intervention with the aim of providing information to help researchers wanting to implement a similar intervention in similar settings or to raise questions for future research, rather than being in preparation for a trial assessing effectiveness/efficacy. Some of these 50 trials also appeared to be small effectiveness studies labelled as a pilot, usually only mentioning feasibility once or twice throughout the paper, with one trial explicitly stating that "Because of organizational changes… we had to stop the inclusion after 46 participants, and the study is consequently defined as a pilot study."[18] For the few trials that were potentially pilot CRTs not reported clearly enough, authors only spoke of future studies in general rather than clearly specifying the study was in preparation for a specific future definitive trial. Related to this, it is of interest to know the proportion of our 18 pilot CRTs that are actually followed by a future definitive trial, and we plan to investigate this in future.

CONCLUSION

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We may have overestimated the reporting quality of pilot CRTs; nevertheless our review demonstrates that reporting of pilot CRTs need improving. The identification of just 18 pilot CRTs between 2011 and 2014, mainly from the UK, highlights the need for increased awareness of the importance of carrying out and publishing pilot CRTs and good reporting so that these studies can be identified. Pilot CRTs should primarily be assessing feasibility, and avoiding formal hypothesis testing for effectiveness/efficacy. Improvement is needed in reporting reasons for the pilot, rationale for the pilot trial sample size, and progression criteria, as well as the enrolment stage of clusters and how the cluster design affects aspects of design such as numbers of participants. We recommend adherence to the new CONSORT extension for pilot trials, in conjunction with the CONSORT extension for CRTs.[3, 4, 7] We encourage journals to endorse the CONSORT statement, including extensions.

CONTRIBUTORS:

SE conceived the study and advised on the design and protocol. CC developed the design of the study, wrote the protocol, and designed the screening/sifting and data extraction sheet. CC performed screening and sifting on all papers identified by the electronic search, and CL carried out validation of the screening/sifting process. CC and CL performed independent data extraction on all papers included in the review. CC conducted the analyses of the data and took primary responsibility for writing the manuscript. All authors provided feedback on all versions of the paper. All authors read and approved the final manuscript. CC is the study guarantor.

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This manuscript is an honest, accurate, and transparent account of the study being reported. No important aspects of the study have been omitted, and any discrepancies from the study as planned have been explained.

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TABLES

Table 1: Pilot CRTs included in this review

Author	Year*	Journal	Title	Cluster
Begh [A1]	2011	Trials	Promoting smoking cessation in Pakistani and Bangladeshi men in the UK: pilot cluster randomised controlled trial of trained community outreach workers	Census lower layer super output areas
Jones [A2]	2011	Pediatric Exercise Science	Promoting fundamental movement skill development and physical activity in early childhood settings: a cluster randomized controlled trial.	Childcare centers
Légaré [A3]	2010	Health Expectations	Training family physicians in shared decision making for the use of antibiotics for acute respiratory infections: a pilot clustered randomized controlled trial.	Family medicine groups
Hopkins [A4]	2012	Health Education Research	Implementing organizational physical activity and healthy eating strategies on paid time: process evaluation of the UCLA WORKING pilot study	Worksites - health and human service organizations
Jago [A5]	2012	International Journal of Behavioral Nutrition and Physical Activity	Bristol girls dance project feasibility trial: outcome and process evaluation results	Secondary schools
Taylor [A6]	2011	Clinical Rehabilitation	A pilot cluster randomized controlled trial of structured goal-setting following stroke	Rehabilitation services
Drahota [A7]	2013	Age and Ageing	Pilot cluster randomised controlled trial of flooring to reduce injuries from falls in wards for older people.	Study areas - bays within hospitals
Frenn [A8]	2013	Journal for Specialists in Pediatric Nursing	Authoritative feeding behaviors to reduce child BMI through online interventions	Classrooms
Gifford [A9]	2012	World Views on Evidence-Based Nursing	Developing leadership capacity for guideline use: a pilot cluster randomized control trial.	Service delivery centers with nursing care for diabetic foot ulcers
Jones [A10]	2013	Journal of Medical Internet Research	Recruitment to online therapies for depression: pilot cluster randomized controlled trial.	Postcode areas
Moore [A11]	2013	Substance Abuse Treatment, Prevention, and Policy	An exploratory cluster randomised trial of a university halls of residence based social norms marketing campaign to reduce alcohol consumption among 1st year students.	Residence halls
Pai [A12]	2013	Implementation Science	Strategies to enhance venous thromboprophylaxis in hospitalized medical patients (SENTRY): a pilot cluster randomized trial	Hospitals
Reeves [A13]	2013	BMC Health Services Research	Facilitated patient experience feedback can improve nursing care: a pilot study for a phase III cluster randomised controlled trial.	Wards
Teut [A14]	2013	Clinical Interventions in Aging	Effects and feasibility of an Integrative Medicine program for geriatric patients-a cluster-randomized pilot study.	Shared apartments
Jago [A15]	2014	International Journal of Behavioral Nutrition and Physical Activity	Randomised feasibility trial of a teaching assistant led extracurricular physical activity intervention for 9 to 11 year olds: Action 3:30	Primary schools
Michie [A16]	2014	Contraception	Pharmacy-based interventions for initiating effective contraception following the use of emergency contraception: a pilot study	Pharmacies
Mytton [A17]	2014	Health Technology Assessment	The feasibility of using a parenting programme for the prevention of unintentional home injuries in the under-fives: a cluster randomised controlled trial.	Children's centres
Thomas [A18]	2014	Trials	Identifying continence options after stroke (ICONS): a cluster randomised controlled feasibility trial	Stroke services

* We extracted the earlier of the print and electronic publication year.

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Table 2: Characteristics of pilot CRTs included in this review

Characteristic	Number of trials (%)
Publication year (earlier of the print and electronic publication date)	
2010[a]	1 (6)
2011	3 (17)
2012	3 (17)
2013	7 (39)
2014	4 (22)
Country	
UK	10 (56)
Canada	3 (17)
USA	2 (11)
Germany	1 (6)
New Zealand	1 (6)
Australia	1 (6)
Method of cluster randomisation[b]	
Simple	1 (8)
Stratified with blocks	9 (69)
Blocked only	2 (15)
Bias coin method	1 (8)
Number of clusters randomised[c]	
Median (IQR)	8 (4 to 16)
Range	2 to 50
Average cluster size[d]	
Median (IQR)	32 (14 to 82)
Range	7 to 588

[a] 1 paper has an extracted publication year outside of the 2011 to 2014 range. This is because the print publication date for this paper was 2011 but the online publication date was 2010, so the paper satisfies the inclusion criteria which states that the publication date, print **or** electronic, must be between 2011 and 2014, but we extract the earlier of the print and electronic dates.

[b] 13 of the 18 trials reported their method of randomisation. Percentages are given as a percentage of these 13 trials.

[c] Not reported for 1 trial.

[d] Defined as number of individuals randomised divided by number of clusters randomised, based on 12 trials that reported information on both.

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Table 3: Pilot trial objectives and methods

Characteristic	Number of trials (%)
Primary objective is feasibility [1]	10 (56)
Main feasibility objective given	
Where feasibility is primary objective	
Implementing intervention	6/10 (60)
Recruitment and retention	3/10 (30)
Feasibility of cluster design	1/10 (10)
Where feasibility is not primary objective [2]	
Implementing intervention	3/8 (38)
Recruitment	2/8 (25)
Cluster design	1/8 (13)
Feasibility of trial being able to answer the effectiveness question (and what study design would enable this)	1/8 (13)
Feasibility of larger study	1/8 (13)
Method used to address main feasibility objective given	
Where feasibility is primary objective	
Descriptive statistics and/or qualitative	9/10 (90)
Statistical test	1/10 (10)
Where feasibility is not primary objective	
Descriptive statistics/Qualitative	3/8 (38)
None given/reported elsewhere	5/8 (63)
Rationale for numbers in pilot trial based on formal power calculation for effectiveness/ efficacy [3]	0/8 (0)
Performing any formal hypothesis testing for effectiveness/ efficacy	9/18 (50)
Making any statements about effectiveness/ efficacy without a caveat	4/18 (22)

[1] Where the primary objective was not feasibility, the primary objective was effectiveness/ potential effectiveness and was addressed using statistical tests.
[2] One of the inclusion criteria was that studies were assessing feasibility, but it did not have to be the primary objective
[3] Based on 8 trials that reported a rationale for the sample size of the pilot trial

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Table 4: Number (%) of reports adhering to pilot CRT quality criteria

	Item	Criterion	n(%)
Title and Abstract	1a	Term 'pilot' or 'feasibility' included in the title Identification as a pilot or feasibility randomised trial in the title	15 (83) 12 (67)
	1a	***Term 'cluster' included in the title*** ***Identification as a cluster randomised trial in the title***	12 (67) 12 (67)
Introduction	2a [S]	Scientific background and explanation of rationale for future definitive trial reported Reasons for randomised pilot trial reported	18 (100) 7 (39)
	2a	***Rationale given for using cluster design***	6 (33)
Methods – Trial design	3a	Description of pilot trial design	18 (100)
	3a	***Definition of cluster***	18 (100)
	3b	Reported any changes to methods after pilot trial commencement If yes, reported reasons	5 (28) 5/5 (100)
Methods – Participants	4a	Reported eligibility criteria for participants	13 (72)
	4a	***Reported eligibility criteria for clusters***	9 (50)
	4b	Reported settings and locations where the data were collected	18 (100)
	4c [N]	Reported how participants were identified ***Reported how clusters were identified*** Reported how participants were consented [1] ***Reported how clusters were consented***	9 (50) 6 (33) 13/17 (76) 2 (11)
Methods – Interventions	5	Described the interventions for each group	13 (72)
Methods - Outcomes	6b	Reported any changes to pilot trial assessments or measurements after pilot trial commencement If yes, reported reasons	1 (6) 1/1(100)
	6c [N]	Reported criteria used to judge whether, or how, to proceed with the future definitive trial	3 (17)
Methods – Sample size	7a [S]	Reported a rationale for the sample size of the pilot trial	8 (44)
	7a	***Cluster design considered during the description of the rationale for numbers in the pilot trial***	3 (17)
	7b	Reported stopping guidelines	0 (0)
Methods - Randomisation	8a	Reported method used to generate the random allocation sequence	9 (50)
	8b	Reported randomisation method	13 (72)
	9	Reported mechanism used to implement the random allocation sequence Reported allocation concealment	4 (22) 7 (39)
	10/ ***10a***	Reported who: Generated the random allocation sequence ***Enrolled clusters*** ***Assigned clusters to interventions***	 8 (44) 3 (17) 4 (22)
	10c	***Reported from whom consent was sought*** *Reported whether consent was sought from participants* ***Reported whether consent was sought from clusters*** ***Reported whether participant consent was sought before or after randomisation*** [1]	2 (11) 17 (94) 2 (11) 8/17 (47)
Methods - Blinding	11a	Reported on whether there was blinding Reported who was blinded [2] Reported how they were blinded [2]	10 (56) 6/14 (43) 1/14 (7)
Methods – Analytical methods	***12a***	***Reports clustering accounted for in any of the methods used to address pilot trial objectives/ research questions*** [3]	13/17 (76)
Results – Participant flow	13*	Reports a diagram with flow of individuals through the trial	12 (67)
	13***	***Reports a diagram with flow of clusters through the trial***	10 (56)
	13a/ ***13a*** [S]	Reported number of: Individuals ***(Clusters)*** approached and/or assessed for eligibility [4] Individuals ***(Clusters)*** randomly assigned [4] Individuals ***(Clusters)*** that received intended treatment [4; 4] Individuals ***(Clusters)*** that were assessed for primary objective [4; 4]	 8/17 (47); 10/18 (56) 13/17 (76); 17/18 (94) 8/17 (47); 5/17 (29) 16/17 (94); 14/17 (82)
	13b/ ***13b***	Reported number of: Losses for individuals ***(Clusters)*** after randomisation [4*; 4] Exclusions for individuals ***(Clusters)*** after randomisation [4; 4]	 11/16 (69); 6/17 (35) 1/17 (6); 3/17 (18)
	14a	Reported on dates defining the periods of recruitment	8 (44)

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		Reported on dates defining the periods of follow up	11 (61)
	14b	Reported the pilot trial ended/stopped	0 (0)
Results – Baseline data	15	Reported a table showing baseline characteristics for the individual level If yes, by group	12 (67) 11/12 (92)
	15	***Reported a table showing baseline characteristics for the cluster level*** ***If yes, by group***	2 (11) 2/2 (100)
Results – Outcomes and estimation	17a	Reported results for main feasibility objective (quantitative or qualitative) [5]	13/17 (76)
Results - Harms	19	Reported on harms or unintended effects	4 (22)
	19a [N]	Reported other unintended consequences	0 (0)
Discussion	20 [S]	Reported limitations of pilot trial Reported sources of potential bias Reported remaining uncertainty	17 (94) 10 (56) 10 (56)
	21 [S]	Reported generalisability of pilot trial methods/findings to future definitive trial or other studies	16 (89)
	22	Interpretation of feasibility consistent with main feasibility objectives and findings [5]	12/17 (71)
	22A [N]	Reported implications for progression from the pilot to the future definitive trial	16 (89)
Other information	23	Reported registration number for pilot trial Reported name of registry for pilot trial	11 (61) 11 (61)
	24 [S]	Reported where the pilot trial protocol can be accessed	7 (39)
	25	Reported source of funding	18 (100)
	26 [N]	Reported ethical approval/research review committee approval If yes, reported reference number	17 (94) 8/17 (47)

Item numbers in normal font refer to the item in the CONSORT extension for pilot trials that the quality assessment item is based on.

Item numbers in bold italics refer to the item in the CONSORT extension for CRTs that the quality assessment item is based on.

[N] represents new items in the CONSORT extension for pilot trials compared to the CONSORT 2010 for RCTs.

[S] represents items in the CONSORT extension for pilot trials that are substantially adapted from the CONSORT 2010 for RCTs.

*The CONSORT statements do not include an item 13 but there is a participant flow subheading which strongly recommends a diagram. We therefore reference this subheading as 'item 13' here.

[1] Item not relevant for 1 trial [A12] because they said that the Ethics Board determined it could be conducted without informed consent from patients or surrogates.

[2] Item not relevant for 4 trials [A7, A10, A12, A18] because they reported that blinding was not used.

[3] Item not relevant for 1 trial because no confidence intervals/p-values were given,[A17] so clustering did not need to be accounted for in any of their methods because effect estimates are not biased by cluster randomisation, only confidence intervals/p-values.

[4] Not relevant for 1 trial due to the design of the study.[A10] (This paper was different from the others such that it was not relevant to extract these items. The clusters were postcode areas and they were assessing two online recruitment interventions and comparing the success of the recruitment interventions. As such, participants were those who completed the online questions, and each arm of the study had a "total population ranging from 1.6 to 2 million people clustered in 4 postcode areas")

[4*] Not relevant for 2 trials due to the design of these studies.[A10, A12] (See reason above for A10. For A12, data was collected from medical patient charts so these items were not relevant to extract)

[5] One paper reports the feasibility results in a separate paper so is not included.[A3]

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Table 5: Number (%) of quality assessment criteria reported by each pilot CRT in this review

Study	Overall n(%)*	Title & abstract and Introduction n(%)	Methods n(%)	Results n(%)	Discussion and Other information n(%)
Drahota [A7]	50(70)	6(86)	17(59)	18(78)	9(75)
Pai [A12]	48(69)	5(71)	17(61)	18(78)	8(67)
Mytton [A17]	50(68)	4(57)	21(66)	13(57)	12(100)
Thomas [A18]	46(67)	5(71)	17(59)	15(65)	9(90)
Teut [A14]	49(66)	6(86)	20(63)	14(61)	9(75)
Taylor [A6]	47(64)	7(100)	16(52)	13(57)	11(92)
Légaré [A3]	42(58)	3(43)	18(56)	14(61)	7(64)
Begh [A1]	41(56)	5(71)	16(52)	11(48)	9(75)
Jago [A15]	39(55)	4(57)	11(38)	13(57)	11(92)
Jones [A10]	32(52)	7(100)	10(33)	6(50)	9(75)
Moore [A11]	37(52)	5(71)	13(45)	8(35)	11(92)
Michie [A16]	36(51)	3(43)	15(52)	8(36)	10(83)
Jones [A2]	37(51)	3(43)	15(48)	10(45)	9(75)
Jago [A5]	33(46)	4(57)	13(45)	10(43)	6(50)
Gifford [A9]	33(45)	6(86)	12(39)	8(35)	7(58)
Reeves [A13]	29(41)	6(86)	11(38)	7(32)	5(42)
Frenn [A8]	18(26)	1(14)	5(17)	7(32)	5(42)
Hopkins [A4]	16(23)	2(29)	4(14)	4(18)	6(50)

*This is the overall number(percentage) of the quality assessment items in Table 4 that are reported by each study. The other columns look at this within categories. Note that the denominator varies between studies because not all quality assessment items are relevant for all studies (see footnote of Table 4) and not applicable for some items if a related item is not reported (see items 3b, 6b, 15, 26 in Table 4).

FIGURES

Figure 1: Flow diagram of the identification process for the sample of 18 pilot cluster randomised trials included in this review

APPENDICES

Appendix 1: Search strategy

Appendix 2: Data extracted

Appendix 3: List of studies included in this systematic review

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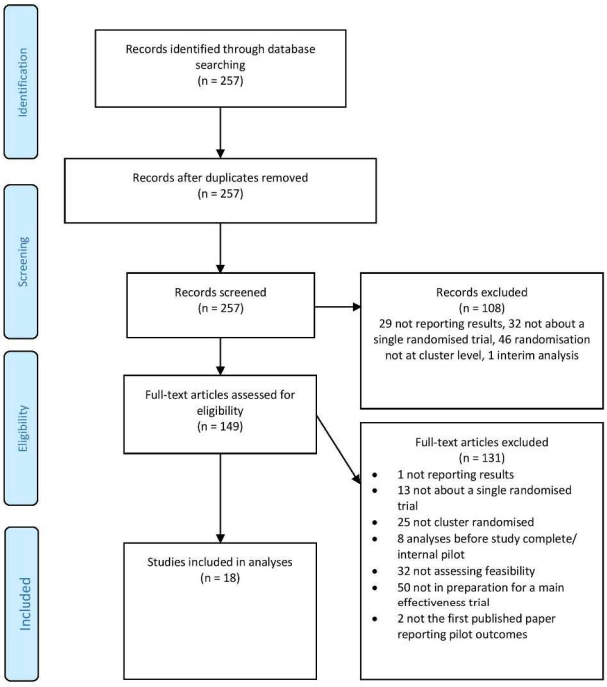

Flow diagram of the identification process for the sample of 18 pilot cluster randomised trials included in this review

210x297mm (300 x 300 DPI)

Appendix 1: Search strategy

#1:	randomised trial [All fields]
#2:	randomized trial [All fields]
#3:	#1 OR #2
#4:	clinical trial [All Fields]
#5:	#3 AND #4
#6:	((cluster randomization) OR (cluster randomisation) OR (cluster) OR (clustered) OR (clustering) OR (clusters) OR (group-randomized) OR (group-randomised) OR (randomisation unit) OR (randomization unit)) [All fields]
#7:	#5 AND #6
#8:	pilot [Title/Abstract]
#9:	feasibility [Title/Abstract]
#10:	#8 OR #9
#11:	#7 AND #10
#12:	protocol [Title]
#13:	#11 NOT #12
#14:	("2011/01/01"[Date - Publication] : "2014/12/31"[Date - Publication])
#15:	#13 AND #14

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Appendix 2: Data extracted

Items	Data extracted	Further information
Descriptives		
Name of first author	Text	
Publication year	Date	The earlier of the print date and electronic date
Journal	Text	
Title	Text	
Country (or countries) in which the trial was set	Text	
Setting where the data were collected	Text	e.g. community, hospital clinic etc.
Pilot trial design	Parallel CRT, factorial CRT, cross-over CRT, other CRT	
What was the cluster?	Text	
Method of cluster randomisation	Text	
Number of clusters randomised	Number	
Number of individuals randomised	Number	
Additional items relating to pilot trial methodology		
Primary objective/ research question of the pilot trial	Text	As specified by the author, else the outcome used in the sample size justification, or else the first objective/ research question mentioned in the abstract or else main text (following a similar method as that used by Diaz-Ordaz et al.[8])
Is the primary objective feasibility?	Yes/No	
Primary objective/ research question measure	Text	
Method used to address primary objective/ research question	Text	Defined as the main method presented for the primary objective/ research question
Main feasibility objective/ research question of the pilot trial	Text	As specified by the author, else the feasibility outcome used in the sample size justification, or else the first feasibility objective/ research question mentioned in the abstract or else main text
Main feasibility objective/ research question measure	Text	
Method used to address main feasibility objective/ research question	Text	Defined as the main method presented for the primary objective/ research question
Is the rationale for numbers in the pilot trial based on formal power calculation for effectiveness (efficacy)?	Yes/no	
Is the paper performing any formal hypothesis testing for effectiveness/ efficacy?	Yes/no	
Is the paper making any statements about effectiveness/ efficacy without a caveat	Yes/no	The caveat must explain that it is an indication of *potential* effectiveness or explain that the study is underpowered
Title and Abstract		
Term 'pilot' or 'feasibility' included in the title	Yes/no	
Identification as a pilot or feasibility randomised trial in the title	Yes/no	Require 'pilot randomised trial' or 'feasibility randomised trial' in the title, or 'pilot study' or 'feasibility study' and 'randomised trial' in the title
Term 'cluster' included in the title	Yes/no	
Identification as a cluster randomised trial in the title	Yes/no	Require 'cluster randomised trial' in the title – don't accept 'clustered' as this can imply correlation rather than cluster randomised
Introduction		
Scientific background and explanation of rationale for future definitive trial reported	Yes/no	
Reasons for randomised pilot trial reported	Yes/no	We specified there needed to be a rationale in the introduction section for the randomised pilot trial, which was not just simply stating the aims/ objectives/outcomes of the pilot trial but gave a clear rationale of why the pilot trial was needed before proceeding to the future definitive trial.

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Rationale given for using cluster design	Yes/no	
Methods – Trial design		
Description of pilot trial design	Yes/no	
Definition of cluster	Yes/no	
Reported any changes to methods after pilot trial commencement If yes, reported reasons	Yes/no Yes/no	
Methods – Participants		
Reported eligibility criteria for participants	Yes/no	
Reported eligibility criteria for clusters	Yes/no	
Reported settings and locations where the data were collected	Yes/no	
Reported how participants were identified	Yes/no	We required that the authors describe the exact way the participants were identified (e.g. during consultations/visits to the cluster, or through advertisement requesting volunteers)
Reported how clusters were identified	Yes/no	We required that the authors describe the exact way the clusters were identified (e.g. all clusters in a particular geographical location, or selection from a register/list etc.)
Reported how participants were consented	Yes/no	
Reported how clusters were consented	Yes/no	
Methods – Interventions		
Described the interventions for each group	Yes/no	
Methods – Outcomes		
Reported any changes to pilot trial assessments or measurements after pilot trial commencement If yes, reported reasons	Yes/no Yes/no	
Reported criteria used to judge whether, or how, to proceed with the future definitive trial	Yes/no	
Methods – Sample size		
Reported a rationale for the sample size of the pilot trial	Yes/no	
Cluster design considered during the description of the rationale for numbers in the pilot trial	Yes/no	We required that the authors show some consideration about clustering during the description of their sample size calculation, even if not formally accounting for it currently but describe during their rationale that they e.g. plan to estimate the design effect in the future definitive trial
Reported stopping guidelines	Yes/no	
Methods – Randomisation		
Reported method used to generate the random allocation sequence	Yes/no	e.g. random numbers table, coin tossing, computer generated random list
Reported randomisation method If yes, randomisation method	Yes/no Text	 e.g. simple, stratification, blocking, matching
Reported mechanism used to implement the random allocation sequence	Yes/no	e.g. sequentially numbered containers, sealed envelopes, central telephone
Reported allocation concealment	Yes/no	
Reported who: Generated the random allocation sequence Enrolled clusters Assigned clusters to interventions	 Yes/no Yes/no Yes/no	 Tick yes for last two points if a 'who' is not relevant since done by e.g. post/online
Reported whether consent was sought from participants	Yes/no	
Reported whether consent was sought from clusters	Yes/no	
Reported from whom consent was sought	Yes/no	I.e. reported both whether consent was sought from participants and whether consent was sought from clusters
Reported whether participant consent was sought before or after randomisation	Yes/no	
Methods – Blinding		
Reported on whether there was blinding	Yes/no	

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Reported who was blinded	Yes/no	tick yes if they report anyone who was blinded, even if they don't report on everyone
Reported how they were blinded	Yes/no	tick yes if they report on how anyone was blinded, even if they don't report on how everyone who was blinded was blinded
Methods – Analytical methods		
Reports clustering accounted for in any of the methods used to address pilot trial objectives/ research questions	Yes/no	
Results – Participant flow		
Reports a diagram with flow of individuals through the trial	Yes/no	
Reports a diagram with flow of clusters through the trial	Yes/no	
Reported number of: Individuals approached and/or assessed for eligibility Individuals randomly assigned Individuals that received intended treatment Losses for individuals after randomisation Exclusions for individuals after randomisation Individuals that were assessed for primary objective	 Yes/no Yes/no Yes/no Yes/no Yes/no Yes/no	
Reported number of: Clusters approached and/or assessed for eligibility Clusters randomly assigned Clusters that received intended treatment Losses for clusters after randomisation Exclusions for clusters after randomisation Clusters that were assessed for primary objective	 Yes/no Yes/no Yes/no Yes/no Yes/no Yes/no	
Results – Recruitment		
Reported on dates defining the periods of recruitment	Yes/no	
Reported on dates defining the periods of follow up	Yes/no	
Reported the pilot trial ended/stopped	Yes/no	
Results – Baseline data		
Reported a table showing baseline characteristics for the individual level If yes, by group	Yes/no Yes/no	
Reported a table showing baseline characteristics for the cluster level If yes, by group	Yes/no Yes/no	
Results – Outcomes and estimation		
Reported results for main feasibility objective (quantitative or qualitative)	Yes/no	
Results – Harms		
Reported on harms or unintended effects	Yes/no	Tick yes even if reported that there were no harms
Reported other unintended consequences	Yes/no	An unintended consequence would be an unexpected result/finding that was not one of the objectives to explore and where the result would have consequences on the future definitive trial, such as a change in design/population etc.
Discussion		
Reported limitations of pilot trial	Yes/no	
Reported sources of potential bias	Yes/no	
Reported remaining uncertainty	Yes/no	
Reported generalisability of pilot trial methods/findings to future definitive trial or other studies	Yes/no	To be reporting on the generalisability of the pilot trial methods/findings to the future definitive trial, we deemed it sufficient for the paper to be discussing whether the methods/findings of the pilot study can be applied to the future definitive trial. To be reporting on the generalisability of the pilot trial methods/findings to other future trials, we deemed it sufficient for the paper to be discussing whether the methods/findings of the pilot study can be applied to other future trials.
Interpretation of feasibility consistent with main feasibility objectives and findings	Yes/no	

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Reported implications for progression from the pilot to the future definitive trial If yes, what were the implications?	Yes/no Proceed/ proceed with changes/ Further research or piloting needed first/ Don't go ahead	
Other information		
Reported registration number for pilot trial	Yes/no	
Reported name of registry for pilot trial	Yes/no	
Reported where the pilot trial protocol can be accessed	Yes/no	
Reported source of funding	Yes/no	
Reported ethical approval/research review committee approval If yes, reported reference number	Yes/no Yes/no	

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Appendix 3: List of studies included in this systematic review

(Note that the publication years given in the list below are the print publication years, rather than the earlier of the print or electronic publication year, so there is some discrepancy between the list below and Table 1)

1. Begh RA, Aveyard P, Upton P, Bhopal RS, White M, Amos A, et al. Promoting smoking cessation in Pakistani and Bangladeshi men in the UK: pilot cluster randomised controlled trial of trained community outreach workers. Trials. 2011;12:197.
2. Jones RA, Riethmuller A, Hesketh K, Trezise J, Batterham M, Okely AD. Promoting fundamental movement skill development and physical activity in early childhood settings: a cluster randomized controlled trial. Pediatr Exerc Sci. 2011;23(4):600-15.
3. Legare F, Labrecque M, LeBlanc A, Njoya M, Laurier C, Cote L, et al. Training family physicians in shared decision making for the use of antibiotics for acute respiratory infections: a pilot clustered randomized controlled trial. Health Expect. 2011;14 Suppl 1:96-110.
4. Hopkins JM, Glenn BA, Cole BL, McCarthy W, Yancey A. Implementing organizational physical activity and healthy eating strategies on paid time: process evaluation of the UCLA WORKING pilot study. Health Educ Res. 2012;27(3):385-98.
5. Jago R, Sebire SJ, Cooper AR, Haase AM, Powell J, Davis L, et al. Bristol girls dance project feasibility trial: outcome and process evaluation results. Int J Behav Nutr Phys Act. 2012;9:83.
6. Taylor WJ, Brown M, William L, McPherson KM, Reed K, Dean SG, et al. A pilot cluster randomized controlled trial of structured goal-setting following stroke. Clin Rehabil. 2012;26(4):327-38.
7. Drahota AK, Ward D, Udell JE, Soilemezi D, Ogollah R, Higgins B, et al. Pilot cluster randomised controlled trial of flooring to reduce injuries from falls in wards for older people. Age Ageing. 2013;42(5):633-40.
8. Frenn M, Pruszynski JE, Felzer H, Zhang J. Authoritative feeding behaviors to reduce child BMI through online interventions. J Spec Pediatr Nurs. 2013;18(1):65-77.
9. Gifford WA, Davies BL, Graham ID, Tourangeau A, Woodend AK, Lefebre N. Developing leadership capacity for guideline use: a pilot cluster randomized control trial. Worldviews Evid Based Nurs. 2013;10(1):51-65.
10. Jones RB, Goldsmith L, Hewson P, Williams CJ. Recruitment to online therapies for depression: pilot cluster randomized controlled trial. J Med Internet Res. 2013;15(3):e45.
11. Moore GF, Williams A, Moore L, Murphy S. An exploratory cluster randomised trial of a university halls of residence based social norms marketing campaign to reduce alcohol consumption among 1st year students. Subst Abuse Treat Prev Policy. 2013;8:15.
12. Pai M, Lloyd NS, Cheng J, Thabane L, Spencer FA, Cook DJ, et al. Strategies to enhance venous thromboprophylaxis in hospitalized medical patients (SENTRY): a pilot cluster randomized trial. Implement Sci. 2013;8:1.
13. Reeves R, West E, Barron D. Facilitated patient experience feedback can improve nursing care: a pilot study for a phase III cluster randomised controlled trial. BMC Health Serv Res. 2013;13:259.
14. Teut M, Schnabel K, Baur R, Kerckhoff A, Reese F, Pilgram N, et al. Effects and feasibility of an Integrative Medicine program for geriatric patients-a cluster-randomized pilot study. Clin Interv Aging. 2013;8:953-61.
15. Jago R, Sebire SJ, Davies B, Wood L, Edwards MJ, Banfield K, et al. Randomised feasibility trial of a teaching assistant led extracurricular physical activity intervention for 9 to 11 year olds: Action 3:30. Int J Behav Nutr Phys Act. 2014;11:114.
16. Michie L, Cameron ST, Glasier A, Larke N, Muir A, Lorimer A. Pharmacy-based interventions for initiating effective contraception following the use of emergency contraception: a pilot study. Contraception. 2014;90(4):447-53.

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17. Mytton J, Ingram J, Manns S, Stevens T, Mulvaney C, Blair P, et al. The feasibility of using a parenting programme for the prevention of unintentional home injuries in the under-fives: a cluster randomised controlled trial. Health Technol Assess. 2014;18(3):1-184.
18. Thomas LH, Watkins CL, Sutton CJ, Forshaw D, Leathley MJ, French B, et al. Identifying continence options after stroke (ICONS): a cluster randomised controlled feasibility trial. Trials. 2014;15:509.

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PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	1, 2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	3
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	3
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	5
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	3, 4
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	4
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Appendix 1
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	4
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	5, 6
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	Appendix 2
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	N/A – review of reporting quality
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	N/A –

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			review of reporting quality
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	N/A – review of reporting quality

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	N/A – review of reporting quality
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	N/A – review of reporting quality
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	6, 7, Figure 1
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	7, Table 1, Appendix 3
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	N/A – review of reporting quality
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	N/A – review of reporting

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PRISMA 2009 Checklist

			quality
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	N/A – review of reporting quality
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	N/A – review of reporting quality
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	N/A – review of reporting quality
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	9, 10, 11
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	12
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	11
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	13

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

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