Methodological Reporting in Feasibility Studies: A Descriptive Review of the Nursing Intervention Research Literature

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ABSTRACT

Background. In reaction to weaknesses in feasibility studies reporting, the CONSORT statement published an extension for feasibility studies in 2016.

Aim. To systematically review and appraise the reporting of feasibility studies in the nursing intervention research literature based on the CONSORT statement extension for feasibility studies.

Method. Papers published prior to January 2018 that described feasibility studies of nursing interventions were retrieved. Components of feasibility studies were coded, and code frequencies were analyzed.

Results. The review included 186 papers. Although most papers (n=142, 76.3%) included the label 'pilot' or 'feasibility' in their title, reporting for other components generally did not adhere to one or several CONSORT recommendations. Most papers reported objectives (n=116, 62.4%), designs (n=95, 51%), or rationales for sample size (n=165, 88.7%) that were incongruent with the purpose of feasibility studies.

Discussion. This review results in two main implications for nursing research. First, we noted that the reporting of feasibility studies is weak. While all papers described feasibility studies, almost half focused exclusively on testing the effectiveness of an intervention. Second, we identified rationales for sample size along with key references that could offer guidance in reporting feasibility studies while being coherent with the CONSORT recommendations.

Key words. Nursing Interventions, Feasibility Study, Pilot Study, Research Design, Research Methodology

BACKGROUND

The number of feasibility studies being published has grown in the last decade and researchers now recognize their importance in the design and evaluation of complex interventions (Craig et al., 2008; Day et al., 2015). In the literature, 'feasibility studies' is an umbrella term that encompasses randomized pilot studies, non-randomized pilot studies, and other non-pilot feasibility studies (Eldridge et al., 2016a; Eldridge et al., 2016b; Feeley and Cossette, 2015b; Feeley and Cossette, 2015a) (see Table 1). The purpose of a feasibility study is not to test the effectiveness of an intervention, but rather to prepare a full-scale trial by investigating features of a research protocol that could hamper its success, such as uncertainties about recruitment procedures or data collection methods (Eldridge et al., 2016a; Eldridge et al., 2016b). Accordingly, feasibility studies are highly valued by funding agencies in their decision to support larger trials.

An ongoing critique of feasibility studies is that they report objectives similar to those of full-scale trials without sufficient statistical power to achieve those aims (Arain et al., 2010; Kistin and Silverstein, 2015). This is problematic, as the results from underpowered studies risk being misinterpreted (over- or underestimation or effect sizes) and lead to biased recommendations regarding the value of an intervention (Arain et al., 2010; Kistin and Silverstein, 2015).

The inconsistent use of the term 'feasibility' is deemed to reflect a lack of agreement and guidance on the conduct and reporting of such studies (Eldridge et al., 2016b). In recent years, the scientific community has come together in hopes of addressing this issue and created guidelines to support the design and reporting of feasibility studies. In 2015, nursing researchers Feeley and Cossette (2015a, 2015b) published guidance on the purpose and conduct of feasibility

studies and highlighted their role in assessing not only the feasibility, but also the acceptability of interventions. One year later, the Consolidated Standards of Reporting Trials (CONSORT) statement—the reference for reporting randomized trials—added an extension for feasibility studies in reaction to severe weaknesses in reporting (Eldridge et al., 2016a). In comparison to the original CONSORT statement, the extension added the following recommendations for reporting key components that are characteristic of feasibility studies:

- In their title, feasibility studies must be clearly identified as such.
- The background of a feasibility study must include the rationale for the larger trial and the reasons for conducting a feasibility study first, which should be coherent with objectives of such studies.
- Objectives that are appropriate for feasibility studies include investigating any component of a research protocol or intervention that is uncertain and could hamper the success of a larger trial (Eldridge et al., 2016a; Eldridge et al., 2016b; Feeley and Cossette, 2015b; Feeley and Cossette, 2015a).
- The study design must be labeled with 'pilot' or 'feasibility' (e.g., pilot randomized controlled trial).
- For sample sizes, authors should provide a rationale for the number of participants recruited but are not expected to report the calculations by which the numbers were determined (e.g., power calculations).

With respect to the latter recommendation, determining the sample size for a feasibility study is a topic of debate. It is widely accepted that power calculations for testing the effectiveness of an intervention (formal hypothesis testing) are not appropriate to determine the sample size for a feasibility study as they are not congruent with the purpose of such study

(Eldridge et al., 2016a). To be congruent with the purpose of feasibility studies, a more acceptable approach is to determine key objectives to be achieved (e.g., recruitment and retention rates), and to adjust numbers to ensure a desired degree of precision around these estimates (Eldridge et al., 2016a). Another approach is to use a proportion (e.g., 10-15%) of the expected sample size of the full-scale trial (Cocks and Torgerson, 2013; Eldridge et al., 2016a; Whitehead et al., 2016).

The extent to which these recommendations have influenced the use and reporting of feasibility studies in nursing intervention research remains unclear. Thus, our objective was threefold: (1) to systematically review the literature on feasibility studies in nursing intervention research; (2) to assess the reporting of characteristic components of feasibility studies in nursing intervention research, based on the CONSORT statement extension for feasibility studies; (3) to identify the rationales and key references used by authors to support the sample sizes in their feasibility studies that are coherent with the CONSORT recommendations.

MATERIALS AND METHODS

This descriptive review (Paré et al., 2015) was conducted to examine literature and assess the reporting of feasibility studies in nursing intervention research. Through structured search methods, descriptive reviews aim to identify interpretable patterns and gaps in the literature with respect to pre-existing propositions, theories, methodologies or findings (Paré et al., 2015). In the descriptive review reported here, following the formulation of our aims we performed 5 steps: 1) developed the search strategy based on key feasibility study literature (for example: Eldridge et al., 2016a; Eldridge et al., 2016b; Feeley and Cossette 2015a, Feeley and Cossette 2015b); 2) conducted a systematic search of multiple databases to identify feasibility studies in nursing intervention research; 3) selected studies using pre-established eligibility criteria; 4)

extracted the data focused on key features of feasibility studies; 5) synthesized and analyzed data.

Steps 1 and 2: Search Strategy and Systematic Search

A search strategy was defined by a librarian in collaboration with review authors. The search strategy used a combination of keywords and medical subheadings related to feasibility studies and nursing interventions (e.g., 'Pilot Projects,' 'Feasibility Studies,' 'Nursing,' 'Intervention').

We searched seven electronic bibliographical databases in January 2018 for eligible primary research articles: Cumulative Index to Nursing and Allied Health Literature (CINAHL), via EBSCOhost; Embase, via Ovid SP; Google Scholar; PsycINFO, via APA PsycNet; PubMed (including MEDLINE), via NCBI; Web of Science—Science Citation Index (SCI) Expanded and Social Sciences Citation Index (SSCI), via Clarivate Analytics.

Step 3: Eligibility Criteria and Selection of Papers

To be included, papers had to describe a feasibility study of a nursing intervention delivered to patients. Nursing intervention was defined as "a treatments, therapies, procedures, or actions implemented by health care professionals to and with clients, in a particular situation, to move the client's condition toward desired health outcomes that are beneficial to the clients" ((Sidani and Braden, 2011), p. 17). In terms of study design, no restrictions were used aside from our search strategy keywords which already included 'Pilot Projects' and 'Feasibility Studies'. Papers written in English and French from 2015 to 2017 were retained to portray the reporting practices around and after the publication of recommendations cited in this paper's introduction (Eldridge et al., 2016a; Eldridge et al., 2016b; Feeley and Cossette 2015a; Feeley and Cossette 2015b).

Exclusion criteria were: (a) secondary analysis, literature review, or meta-analysis; (b) conference abstract; (c) full-scale randomized controlled trial; (d) intervention delivered to healthcare professionals; and (e) intervention not led or delivered by a nurse.

All citations were imported in EndNote X8.1 and duplicates were removed. Based on titles and abstracts, two independent researchers (TM, MHG) screened the first 100 citations. Given the high inter-rater agreement—Kappa reached 0.86 (95% CI, 0.84–0.88)—the remaining citations (n=909) were split into two equal sets and each was screened by one researcher (TM or MHG). When a researcher doubted whether to include a citation or not, another researcher (PL) examined the citation and consensus was reached by discussion. Following this, full texts were retrieved for the papers selected, and additional papers were excluded per criteria described above.

Step 4: Data Extraction

Five researchers (TM, MHG, PL, MAMC, GF) extracted the following data for included studies: year of publication, journal, country, specialty, title, objectives, study design, and rationale for sample size. Double data extraction was performed for 12% of the sample as suggested for medical record review (Worster and Haines, 2004). As the extractor agreement was high, the rest of the data was extracted by only one extractor for remainder of the sample.

Step 5: Data Synthesis and Analysis

Studies were first codified to extract characteristics of interest; each study was treated as a unit of analysis. Then, a frequency analysis was conducted to identify patterns in order "to represent the state of the art in a research domain" (Paré et al. 2015, p. 186). Descriptive statistics (frequencies) were used to report the year of publication, journal, country, and specialty. For titles, objectives, and designs, papers were coded based on labels used by authors:

223 'pilot,' 'acceptability,' 'feasibility,' or 'effectiveness' (including 'efficacy,' 'effect,' or
224 'impact'). Additional wording used to characterize a study's aim (e.g., 'refining' or
225 'developing' an intervention, 'preliminary' assessment of the intervention) or design (e.g.,
226 'randomized,' 'qualitative') were also coded. These labels were selected based on the
227 CONSORT guidelines and the writings of key authors in the pilot literature (Arain et al., 2010;
228 Cocks and Torgerson, 2013; Eldridge et al., 2016a; Eldridge et al., 2016b; Feeley and Cossette,
229 2015b; Feeley and Cossette, 2015a; Hertzog, 2008; Lancaster et al., 2004; Leon et al., 2011;
230 Thabane et al., 2010). Based on this literature, we identified labels that reflect adequate
231 elements of feasibility studies and others that reflect a misconception (Table 2). Descriptive
232 statistics were also stratified by year of publication to identify any trends relative to
233 publications before or after the publication of the CONSORT recommendations.

234 As the guidance for the appropriate rationales to support the sample size in feasibility
235 studies is still vague, we coded the rationales for sample sizes from the papers using an
236 inductive coding procedure, i.e., creating and adjusting codes depending on what was described
237 in the papers. The analysis was mainly descriptive and based on the frequencies of codes for
238 each category of interest.

239 **RESULTS**

240 The flowchart of the literature is presented in Figure 1. Title and abstracts were screened
241 for 909 papers. Following this, full texts were retrieved for the papers selected (n=206), and
242 additional papers were excluded per criteria described above (n=20). Leaving 186 papers to be
243 included in the analyses.

244 Papers included in the review were published in 2015 (n=83, 44.6%), 2016 (n=67,
245 36.0%), and 2017 (n=36, 19.4%); see Supplemental Digital Content 1 for the list of papers

reviewed. Papers were published in 116 different journals (Supplemental Digital Content 1). Papers originated from North America (n=105, 56.5%), Asia (n=36, 19.4%), Europe (n=26, 14.0%), Oceania (n=13, 7.0%) and South America (n=4, 2.2%). The most frequent specialties were geriatrics (n=32, 17.2%), pediatrics (n=24, 12.9%), oncology (n=28, 15.1%), and chronic care (n=25, 13.4%).

The majority of papers included the label 'pilot' or 'feasibility' in their title (n=142, 76.3%); the remainder included 'pilot' or 'feasibility' in their abstract (n=32, 17.2%) or main text (n=12, 6.5%). Beside the label 'pilot' or 'feasibility,' the title of 26 papers (14%) included labels suggesting formal hypothesis testing (e.g., 'efficacy,' 'effectiveness,' 'effect' or 'impact').

As presented in Table 3, the objectives reported in 69 papers (37.1%) were solely to refine an intervention/protocol, or to test its acceptability or feasibility. In 32 papers (17.2%), objectives related to the feasibility and acceptability of an intervention/protocol were combined with objectives to test the effectiveness of an intervention. One paper's objective was to calculate the sample size for a larger trial. In the rest of the papers (n=84, 45.2%), objectives were solely to investigate the 'efficacy,' 'effectiveness,' 'effect,' or 'impact' of an intervention.

In 91 papers (48.9%), the study design was characterized with the label 'pilot' or 'feasibility,' 88 papers (47.3%) reported a study design without using the word 'pilot' or 'feasibility'. Although the included papers had either 'Pilot Projects' and 'Feasibility Studies' in the title as per our search keywords, seven papers (3.8%) did not specify any study design within their main text. Among papers that described a design, descriptors included: 'randomized' (n=76, 40.9%), 'quasi-experimental' (n=68, 36.6%), 'mixed' (n=19, 10.2%), 'observational' (n=10, 5.4%) and 'qualitative' (n=6, 3.2%).

The majority of papers (n=125, 67.2%) did not report any rationale to support their sample size. The other papers (n=61, 32.8%) reported one or several rationales, including power calculations (n=40, 21.5%), sample size of previous feasibility studies (n=17, 9.1%), expected effect size of an intervention (n=12, 6.5%), various methodological references from the feasibility study literature (n=11, 5.9%), or qualitative data saturation (n=3, 1.6%). Among the methodological references identified in this review (Cocks and Torgerson, 2013; Feeley et al., 2009; Hertzog, 2008; Kraemer et al., 2006; Lancaster et al., 2004; Leon et al., 2011; Thabane et al., 2010), the confidence interval approach (degree of precision) was the most frequent (n=4; (Eldridge et al., 2016a; Hertzog, 2008; Thabane et al., 2010). Of note, sample sizes were increased in anticipation of attrition rates in 12 papers (6.5%).

Considering these characteristics and the codification scheme prepared for the analysis in this descriptive review, we observed that although most papers (n=142, 76.3%) included the label 'pilot' or 'feasibility' in their title, reporting for the other components was generally not coherent with the reporting standards. As presented in Table 4, most papers reported objectives (n=116, 62.4%), designs (n=95, 51%), or rationales for sample size (n=165, 88.7%) that were incongruent with the purpose of feasibility studies. These results did not differ when stratified by year of publication.

DISCUSSION

This systematic descriptive review appraised the reporting of 186 feasibility studies in the nursing intervention research literature and found that the majority did not adhere to one or several recommendations of the CONSORT statement extension for feasibility studies. The observations from this descriptive review result in two important contributions. First, our results highlight that this design remains misused as a large proportion of feasibility studies in the

nursing intervention literature still focuses on hypothesis testing rather than on acceptability and feasibility of research protocols or interventions. Indeed, we observed that while most papers included the label 'pilot' or 'feasibility' in their title, the majority reported objectives, designs, or rationales for sample size that were not consistent with the purpose of feasibility studies. The purpose of feasibility studies is to investigate features of a research protocol or intervention that could hamper the success of a full-scale trial (Eldridge et al., 2016a; Eldridge et al., 2016b; Feeley and Cossette, 2015b; Feeley and Cossette, 2015a). Second, our results highlight the rationales used in nursing intervention feasibility studies to support the sample size. As guidance on the subject remains vague, highlighting the rationales that are coherent with the purpose of feasibility studies and the references to support these rationales will inform the nursing scientific community and may contribute to better practice in reporting feasibility studies.

Perhaps the most interesting but concerning finding from this review was the large number of papers misleadingly claiming to report on a feasibility study, when in fact they were presenting results regarding the effectiveness of an intervention. While all papers described feasibility studies, almost half of the papers focused exclusively on testing the effectiveness of an intervention. This goes against the purpose of the feasibility study design, which should not aim to test hypotheses regarding the effectiveness of an intervention (Arain et al., 2010). Another concerning finding was the lack of rationale to support sample sizes in more than sixty percent of the papers included in the review, and the presentation of power calculations to support sample sizes in twenty percent of the papers. This means that the vast majority of the papers reviewed did not follow the CONSORT recommendations regarding sample sizes, an issue that probably reflects misunderstandings regarding the purpose of the feasibility study

315 design.

316 These results are consistent with previous reviews in which poor reporting of feasibility
317 studies in various fields was highlighted (Arain et al., 2010; Eldridge et al., 2016a; Eldridge et
318 al., 2016b; Lancaster et al., 2004). However, this is the first review to focus on the field of
319 nursing intervention research. Considering the importance of intervention development and
320 testing in nursing scholarship, it appears as a field conducive to the improvement of reporting
321 practices for feasibility studies. However, the results of this review show that the
322 recommendations for reporting feasibility studies have yet to have an impact in the field of
323 nursing intervention research.

324 Nevertheless, some papers exemplified best practices for reporting feasibility studies. For
325 example, Walker, Aitken, Huxley and Juttner (2015) reported on a protocol for a pilot study to
326 evaluate the feasibility of study administration, resource and data management, intervention
327 fidelity and effect size of a prophylactic dressing intervention to minimize sacral pressure.
328 Verloo, Goulet, Morin, and von Gunten (2016) investigated the feasibility and acceptability of
329 delirium assessment methods in the context of home care for a randomized controlled trial.
330 Cossette et al. Cossette et al. (2017) assessed the feasibility, acceptability, and preliminary
331 efficacy of a nursing intervention to enhance patient acceptance of implantable cardioverter
332 defibrillators. In all three cases, titles and designs clearly included the label 'pilot' or
333 'feasibility', objectives were congruent with the purpose of feasibility studies, and rationales for
334 sample sizes are provided without involving power calculations for hypothesis testing.

335 **Limitations**

336 It could be argued that the timespan that this review covered was relatively close to the
337 publication date of the recommendations; the review could be repeated in a few years to get a

338 better sense of the impact that the recommendations had on the reporting of feasibility studies
339 in nursing intervention research.

340 ## CONCLUSION AND RECOMMENDATIONS

341 In this descriptive review, we have systematically reviewed the literature on feasibility studies in
342 nursing intervention research and appraised the reporting of characteristic components of feasibility
343 studies in nursing intervention research, based on the CONSORT statement extension for feasibility
344 studies. Our results highlight that the reporting of feasibility studies is still poor. This study design
345 remains misused, as evidenced by the fact that a large proportion of feasibility studies in the
346 nursing intervention research literature still focus on hypothesis testing.

347 Another objective was to identify the rationales and key references to support sample
348 sizes in feasibility studies in nursing intervention research. We found that the confidence
349 interval approach (degree of precision) was the most frequent. Additionally, key
350 methodological references used by authors of feasibility studies in nursing intervention
351 research, that are coherent with CONSORT recommendations, were highlighted in this review
352 (Cocks and Torgerson, 2013; Feeley et al., 2009; Hertzog, 2008; Kraemer et al., 2006;
353 Lancaster et al., 2004; Leon et al., 2011; Thabane et al., 2010).

354 Based on the results of this descriptive review, we would argue that there is a need for
355 more sensitization and education regarding the purpose, conduct, and reporting of feasibility
356 studies among the nursing scientific community, and that there is a need for more scrutiny of any
357 manuscript that claims to report on a feasibility study.

358 ## KEY POINTS FOR RESEARCH

359 - The results of this descriptive review highlight that the reporting of feasibility studies is
360 still weak;

- The findings highlight that this study design remains misused, as evidenced by the fact that a large proportion of feasibility studies in the nursing intervention research literature still focus on hypothesis testing.
- In terms of rational to support sample sizes in feasibility studies, this descriptive review found that the confidence interval approach (degree of precision) was the most frequent.
- Results of this descriptive review suggest that there is a need for more sensitization and education regarding the purpose, conduct, and reporting of feasibility studies among the nursing scientific community.

ETHICAL PERMISSIONS

Ethical permissions were not required for this work as it is a literature review and does not involve any participants.

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426 **Figure 1. Flow Diagram of the article selection process**

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428

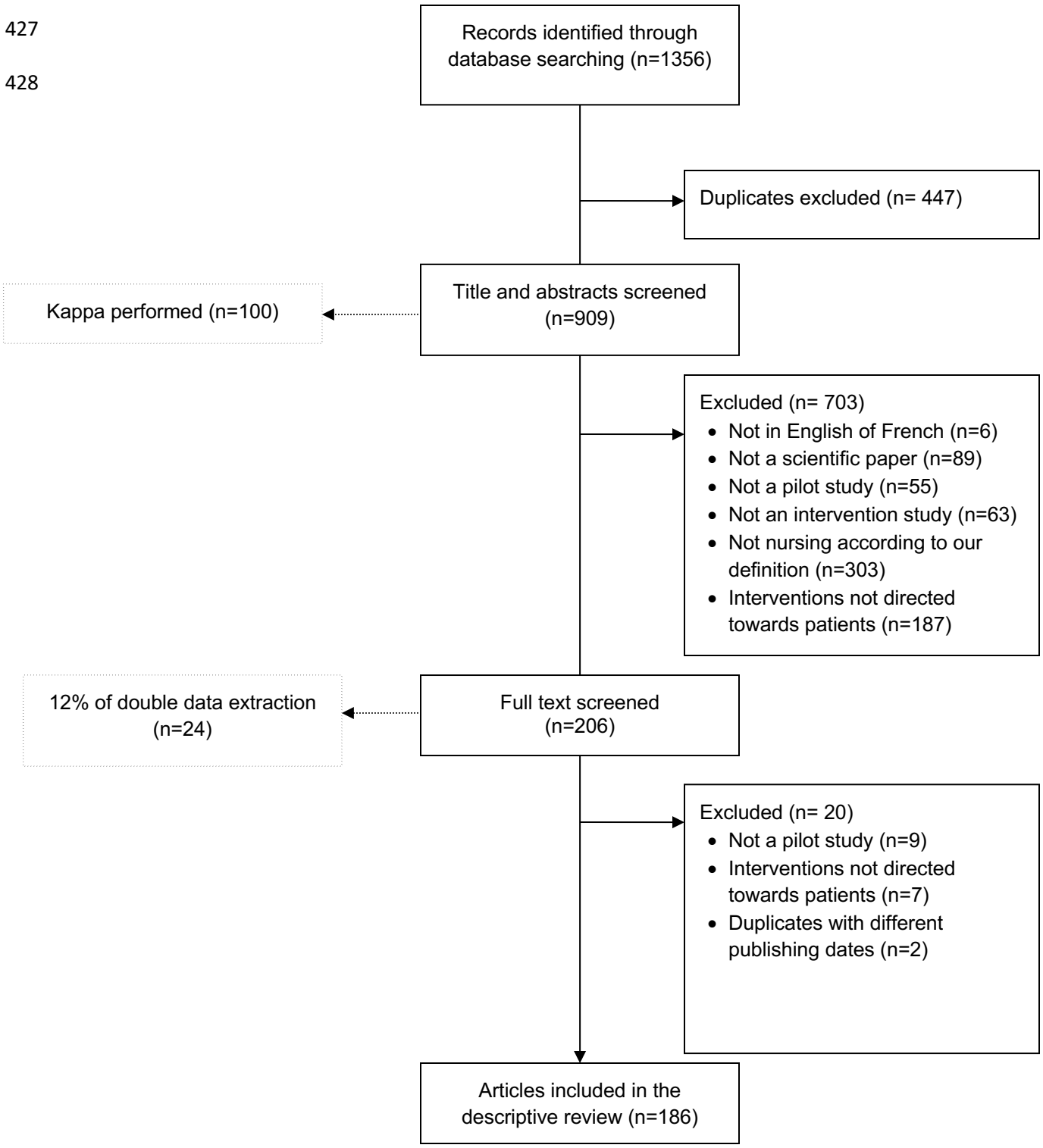

Table 1. Distinction of the subtypes of feasibility studies.

Type of Study		**Definitions from *Defining Feasibility and Pilot Studies in Preparation for Randomized Controlled Trials: Development of a Conceptual Framework* (Eldridge et al 2016b).**
Feasibility studies	Randomized pilot studies	"Studies in which the future RCT, or parts of it, including the randomization of participants, is conducted on a smaller scale (piloted) to see if it can be done. Thus, randomized pilot studies can include studies that for the most part reflect the design of a future definitive trial but, if necessary due to remaining uncertainty, may involve trying out alternative strategies, for example, collecting an outcome variable via telephone for some participants and online for others."
	Non-randomized pilot studies	"Studies in which all or part of the intervention to be evaluated and other processes to be undertaken in a future trial is/are carried out (piloted) but without randomisation of participants."
	Other non-pilot feasibility studies	"Studies that are not pilot studies are those in which investigators attempt to answer a question about whether some element of the future trial can be done but do not implement the intervention to be evaluated or other processes to be undertaken in a future trial, though they may be addressing intervention development in some way."

Table 2. Codification scheme for data analysis.

Characteristics of feasibility studies	Labels representing adequate understanding - congruent with reporting standards	Labels reflecting misconception of elements - incongruent or with reporting standards or incomplete
Title	'pilot,' 'acceptability,' 'feasibility,' 'preliminary effectiveness' 'preliminary efficacy,' 'preliminary effect,' 'preliminary impact'	'effectiveness,' 'efficacy,' 'effect,' 'impact' ** without any wording associated with preliminary assessments.*
Objectives	'assessment of acceptability,' 'assessment of feasibility,' 'refining an intervention,' 'developing an intervention,' 'preliminary assessment of the intervention'	'assessing effectiveness,' 'assessing efficacy,' 'assessing effect,' 'assessing impact,' ** any wording associated with hypothesis testing relative to the intervention's effect.*
Study design	'pilot,' 'acceptability,' 'feasibility,' AND 'randomized,' 'non-randomized,' 'quasi-experimental,' 'qualitative,' 'mixed,' 'pre-post,' 'observational' ** any wording describing the study design.*	No use of the word pilot or feasibility or acceptability. Study design not identified in the paper.
Rationale for the sample sizes	Labels were determined based on papers (see analysis section).	
	As per the CONSORT recommendations, a rationale was expected for the number of participants recruited but we were not expecting calculations by which the numbers were determined (e.g., power calculations).	Rationale relative to hypothesis testing or no rationale provided at all to explain the choice of sample size.

435 **Table 3. Descriptive Statistics for Characteristics of Feasibility Studies.**

	Papers (N=186) n (%)
Title	
A combination of the labels 'feasibility' and/or 'pilot'	142 (76.3)
Preliminary effectiveness' and/or 'preliminary efficacy' and/or 'preliminary effect' and/or 'preliminary impact'	1 (0.5)
A formulation suggesting hypothesis testing	40 (21.5)
With the labels 'feasibility' and/or 'pilot'	26 (14)
Without the labels 'feasibility' and/or 'pilot'	14 (39.9)
Objectives	
The labels 'feasibility' and/or 'pilot'and/or intervention refinement	69 (37.1)
A combination of the labels 'feasibility' and/or 'acceptability' paired with hypothesis testing	32 (17.2)
Calculate the sample size for the larger trial	1 (0.5)
A formulation suggesting hypothesis testing	84 (45.2)
Study Design	
The labels 'feasibility' and/or 'pilot'	91 (48.9)
Other research design without the labels 'feasibility' and/or 'pilot'	88 (47.3)
No study design mentioned	7 (3.8)
Type of design reported	
Randomized	76 (40.9)
Quasi-experimental	68 (36.6)
Mixed	19 (10.2)
Observational	10 (5.4)
Qualitative	6 (3.2)
Sample Size	
Rationale to support sample size choice reported *(1 or more of the following reasons reported):*	61 (32.8)
Power calculations	40 (21.5)
Sample size of previous feasibility studies	17 (9.1)
Expected effect size of an intervention	12 (6.5)
Qualitative data saturation	3 (1.6)
Based on feasibility study literature	11 (5.9)
No rationale to support sample size choice	125 (67.2)

436

437

438 **Table 4. Congruency with Reporting Standards.**

Design Element	Papers congruent[a] with reporting standards	Papers presenting incongruent or incomplete[a] reporting
	n (%)	
Title	142 (76.3)	44 (23.7)
Objectives	70 (37.6)	116 (62.4)
Study design	91 (48.9)	95 (51)
Rationale for the sample size	21 (11.3)	165 (88.7)
Note. [a] Based on the definitions presented in Table 2.		

439