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A METHODOLOGICAL SURVEY ON REPORTING OF PILOT AND FEASIBILITY TRIALS FOR PHYSIOTHERAPY INTERVENTIONS: A STUDY PROTOCOL

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Manuscripts

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3 1 **A METHODOLOGICAL SURVEY ON REPORTING OF PILOT AND**
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5 2 **FEASIBILITY TRIALS FOR PHYSIOTHERAPY INTERVENTIONS: A**
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7 3 **STUDY PROTOCOL**
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27 **AUTHORS' CONTRIBUTIONS**

28 LFCS wrote the first draft. LFCS, LCMC and MA incorporated comments from
29 authors on successive manuscripts. LT, AM and LCMC conceptualized the study.
30 All authors contributed to design of the study, reviewed and approved the
31 manuscript.

32 **COMPETING INTEREST**

33 The authors have no conflicts of interest to declare.

35 **ABSTRACT**

36 **Introduction:** Pilot and feasibility trials aim to test whether a full trial can be
37 conducted or if any procedures must be changed for the full trial. Pilot trials must be
38 reported in a transparent, accurate and complete way. In this report, we present a
39 protocol for a methodological survey with the following aims: 1) determine the
40 percentage of physiotherapy trial reports which claim to be pilot or feasibility trials
41 which evaluate feasibility; 2) determine the aspect of feasibility evaluated in the
42 primary objective(s) of the pilot or feasibility trials; 3) describe the completeness of
43 reporting of abstracts and full articles of pilot or feasibility trials using the
44 CONSORT extension to randomised pilot and feasibility trials, and 4) investigate
45 factors associated with completeness of reporting of pilot or feasibility trials.

46 **Methods and analysis:** Reports of randomised controlled trials indexed in the
47 Physiotherapy Evidence Database (PEDro) that claim to be pilot or feasibility trials
48 and published in 2010-2017 will be included. Two independent reviewers will
49 confirm eligibility and classify the aspect of feasibility being evaluated in the

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3 50 objective(s) of the included pilot or feasibility trials. Completeness of reporting of
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5 51 both the abstract and full article will be evaluated using the CONSORT extension to
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7 52 randomised pilot and feasibility trials. The primary analysis will be a descriptive
8
9 53 analysis about reporting quality of abstracts and full texts of pilot and feasibility
10
11 54 trials. We will use Generalized Estimating Equations (GEE) to explore factors
12
13 55 associated with completeness of reporting.

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15
16 56 **Ethics and dissemination:** The results of this study will be disseminated by
17
18 57 presentation at conferences and will be submitted for publication in a peer reviewed
19
20 58 journal. Ethical approval is not necessary for this study.

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23
24 60 **Key words:** Pilot, Feasibility, Vanguard, Dress rehearsal, Clinical trial.

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27 62 **Strengths and limitations of this study**

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30 63 • The results from this study will help improve the transparency in reporting
31
32 64 pilot and feasibility trials, allowing clinicians and readers to better
33
34 65 understand findings of this type of trials.
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36 66 • This study will be the first to evaluate the quality of reporting of abstracts
37
38 67 and full articles of pilot or feasibility trials for an entire health discipline
39
40 68 (physiotherapy).
- 41
42 69 • The findings of this study are likely to provide guidance for authors, journal
43
44 70 editors and peer reviewers on how to report and review pilot and feasibility
45
46 71 trials.
- 47
48 72 • Findings from the present study are restricted to physiotherapy pilot or
49
50 73 feasibility trials, so our results may not be generalisable to other areas of
51
52 74 healthcare.
- 53
54 75

76 INTRODUCTION

77 Pilot and feasibility trials are exploratory studies that aim to investigate
78 whether the crucial components of planning or preparing for a larger and definitive
79 randomised controlled trial will be viable.^{1,2} They are intended to provide useful
80 information with regards to planning complex interventions (e.g. identifying the
81 optimal dose, testing safety); testing study procedures (e.g. the form of
82 randomisation, estimation of recruitment rate, plausibility of multicentre
83 collaborations); investigating surrogate outcomes or estimating parameters to help
84 to perform sample size calculation.^{3, 4} Although pilot and feasibility trials have
85 slightly different definitions, both are designed to establish whether the main or
86 definitive trial can and should be conducted in the future, and, if so, to determine
87 how the main trial should be done.⁵ Pilot and feasibility trials are designed to ensure
88 that the main trial will be achievable, rigorous and economically justifiable in order
89 to avoid waste of resources.⁴ However, without a clear understanding of how the
90 pilot or feasibility trial was conducted, researchers and clinicians would not be able
91 to judge the methodological quality and to clinically appraise the published report
92 of the trial.

93 Evaluations of published pilot and feasibility trials suggests that the trials
94 may not actually be evaluating feasibility^{6,7} and are being poorly reported.⁷ In a
95 small sample of 93 pilot and feasibility trials published in Indian biomedical
96 journals, 68% of trials performed between-group statistical comparisons and none
97 reported feasibility objectives⁷. In addition, an ad-hoc list of trial characteristics was
98 used to evaluate reporting, rather than a scale or checklist. Another survey of 191
99 pilot and feasibility trials published in 1987-2015 in a single journal (i.e. *Clinical*
100 *Rehabilitation*)⁶ revealed that 110 (58%) trials actually tested feasibility for a future

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3 101 trial, with only 23 trials being followed by a definitive trial.⁶ This implies that the
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5 102 terms “pilot” or “feasibility” may be being incorrectly used to assist in the
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7 103 publication of small trials rather than to systematically test procedures to inform the
8
9 104 conduct of a large definitive trial. Since those evaluations were published, the
10
11 105 methods for evaluating the quality of reporting of pilot and feasibility trials have
12
13 106 improved substantially with the introduction of an extension of the Consolidated
14
15 107 Standards of Reporting Trials (CONSORT) statement specifically for randomised
16
17 108 pilot and feasibility trials.^{8,9} This extension consists of a 40-item checklist for full
18
19 109 articles and a 16-item checklist for abstracts.

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21
22 110 The completeness of reporting of full published reports of randomised
23
24 111 controlled trials¹⁰⁻¹⁵ and the abstracts of trials¹⁶⁻¹⁸ have been evaluated to be sub-
25
26 112 optimal across all areas of healthcare, including in physiotherapy.^{11, 13-15, 19} Factors
27
28 113 which appear to be associated with improved reporting quality include publication
29
30 114 in a journal with a high impact factor,²⁰⁻²² being a multicentre trial,^{23, 24, 21, 25} higher
31
32 115 number of authors,^{21, 26} publication in a journal that endorses the CONSORT
33
34 116 statement,^{12,13,19} language of publication,^{15,21,25} discipline of physiotherapy,²⁷
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36 117 evaluation of electrotherapy interventions,¹⁹ year of publication,^{13, 28} receiving
37
38 118 funding,¹⁴ sample size,^{14,29} and evidence of clinical trial registration.^{13, 19}

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41 119 To our knowledge, the reporting quality of pilot and feasibility trails of
42
43 120 interventions using the new extension of the CONSORT statement for randomised
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45 121 pilot and feasibility trials has not yet been performed for an entire discipline of
46
47 122 healthcare, nor the factors associated with better reporting identified.

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51 124 **OBJECTIVES**

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54 125 The purpose of this methodological survey is to describe the quality of
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3 126 reporting of abstracts and full articles of pilot or feasibility trials for an entire health
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5 127 discipline (physiotherapy). Specifically, the first aim is to determine the percentage of
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7 128 trial reports which claim to be pilot or feasibility trials which evaluate feasibility.
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9 129 Second, to determine the aspect of feasibility evaluated in the primary objective(s)
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11 130 of the true pilot or feasibility trials. Third, to describe the completeness of reporting
12
13 131 of abstracts and full articles using the CONSORT extension for randomised pilot
14
15 132 and feasibility trials. Fourth, to investigate factors associated with completeness of
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17 133 reporting of pilot or feasibility trials.
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22 135 **METHODS**

23 136 **Study design**

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26 137 This study is a methodological survey of completeness of reporting of
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28 138 abstracts and full articles of pilot or feasibility trials for physiotherapy interventions.
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32 140 **Eligibility criteria**

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35 141 We will include all reports of randomised controlled trials indexed in the
36
37 142 Physiotherapy Evidence Database (PEDro; www.pedro.org.au) that claim to be a
38
39 143 pilot or feasibility trial. We will only include trials published in 2011-2017 which
40
41 144 are fully indexed in PEDro (in-process trials, which have not had search terms and
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43 145 PEDro scores allocated, will not be included). We decided to only include trials
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45 146 published after 2010 because the International Committee of Medical Journal
46
47 147 Editors (ICMJE) stated that all trials started after July 2005 should be registered in a
48
49 148 free, publicly available and electronically searchable register^{30, 31} and also because
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51 149 the CONSORT statement was first published in 2010. There will be no language
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53 150 restrictions.
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3 151 We selected the PEDro database as the source of trial reports because it is
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5 152 one of the most comprehensive indexes of reports of randomised controlled trials
6
7 153 evaluating physiotherapy interventions^{32, 33} plus nearly all trials indexed are rated
8
9 154 for methodological quality and the completeness of statistical reporting using the
10
11 155 PEDro scale³⁴ and are coded for the area (or subdiscipline) of physiotherapy
12
13 156 practice and type of intervention. To be eligible for inclusion on PEDro, trials must
14
15 157 involve comparison of at least two interventions (or an intervention and control
16
17 158 condition) applied to subjects who are representative of those who the interventions
18
19 159 might be applied to in the course of clinical practice, with at least one of the
20
21 160 interventions under evaluation being part of physiotherapy practice. In addition, all
22
23 161 trials included in PEDro must involve random (or intend-to-be-random) allocation
24
25 162 of subjects into interventions, and be fully published in a peer-reviewed journal.³⁵
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31 164 **Search strategy**

32
33 165 To identify reports of pilot or feasibility trials a search on PEDro database
34
35 166 will be conducted for the period from 2011 to 2017. We will use “Clinical trial” in
36
37 167 the Method field combined with the following search terms in the Abstract & Title
38
39 168 field: Pilot* OR Feasibility* OR Vanguard* OR “Dress rehearsal”.
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43 44 170 **Studies selection**

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46 171 Two independent reviewers will screen the title and abstracts of the trials in
47
48 172 the search results to identify trials which claim to be a pilot or feasibility trial. The
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50 173 title, abstract and, if necessary, full-text of these self-identified pilot or feasibility
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52 174 trials will be evaluated to identify the sub-set of articles which contain objective(s)
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3 175 linked with feasibility. Any disagreements between reviewers will be resolved by
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5 176 discussion or, if necessary, arbitration by a third reviewer.
6

7 177 Figure 1 presents the flow diagram used to guide article selection.
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9 178 *Insert figure 1 here*
10

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13 180 **Data extraction**

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16 181 Two independent reviewers will classify the pilot or feasibility objective(s)
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18 182 for each included trial. The four categories will be: 1) process (steps that need to
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20 183 take place as part of the main study), 2) resources (time and budget), 3)
21
22 184 management (human and data optimization) or 4) scientific (issues like treatment
23
24 185 safety).⁴ If more than one category is identified for an included trial, we will code
25
26 186 for all relevant categories and indicate which category is linked to the primary
27
28 187 objective of the trial. The number of subjects randomised and whether the pilot or
29
30 188 feasibility trial recommends that a large-scale trial will be conducted will also be
31
32 189 recorded.
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35 190 The two independent reviewers will also complete the CONSORT pilot and
36
37 191 feasibility trials checklist (40 items) and the CONSORT pilot and feasibility trials
38
39 192 abstracts checklist (16 items; note, the “author” item was omitted as this relates to
40
41 193 conference abstracts only) for each trial.^{8,9} The CONSORT checklists include items
42
43 194 related to the title, trial design, methods, results, conclusions, registration and
44
45 195 funding. Each item will be rated as “Reported”, “Inadequately reported”, “Not
46
47 196 reported” or “Not Applicable”. Summary scores for the CONSORT pilot and
48
49 197 feasibility trials checklist (range, 0 to 40) and CONSORT pilot and feasibility trials
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51 198 abstracts checklist (range, 0 to 16) will be calculated by tallying the items scored as
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53 199 “Reported”.
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3 200 The reviewers will independently extract the data using an electronic data
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5 201 extraction form designed for this survey. The data extraction form will be created
6
7 202 using information from the CONSORT extension to randomised pilot and feasibility
8
9 203 trials. We will pilot the data extraction forms on ten randomly selected trials before
10
11 204 proceeding with full data extraction to ensure all reviewers extract data consistently
12
13 205 and to ensure the data extraction form is unambiguous and free from errors.
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15 206 Discrepancies between the two reviewers will be resolved by discussion and by
16
17 207 consulting the published explanation of the CONSORT checklists. If necessary,
18
19 208 arbitration by a third reviewer will help provide consensus on the data extracted.
20
21 209 Kappa coefficients will be calculated for each stage of screening and data collection
22
23 210 to determine the agreement between the independent reviewers.
24
25

26 211 PEDro scale scores, subdiscipline of physiotherapy, intervention, language
27
28 212 of publication and year of publication will be downloaded from PEDro. The PEDro
29
30 213 scale is an 11-item scale which methodological quality and completeness of
31
32 214 statistical reporting of reports of randomised controlled trials.³⁴ The items are: 1)
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34 215 eligibility criteria and source of subjects; 2) random allocation; 3) concealed
35
36 216 allocation; 4) baseline comparability; 5) blinding of subjects; 6) blinding of
37
38 217 therapists; 7) blinding of assessors; 8) > 85% follow-up; 9) intention-to-treat
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40 218 analysis; 10) between-group statistical comparisons; and 11) reporting of point
41
42 219 measures and measures of variability.³⁴ Each item is rated as “yes” (unambiguously
43
44 220 achieved) or “no”, with the number of “yes” responses for items 2-11 tallied to give
45
46 221 the total PEDro score (out of 10). Both the individual items (coded as “0” for “no”
47
48 222 or “1” for “yes”) and the total PEDro score (range, 0 to 10) will be downloaded.
49
50 223 The subdiscipline of physiotherapy codes are: cardiothoracic, continence and
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52 224 women’s health, ergonomics and occupational health, gerontology, musculoskeletal,
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225 neurology, oncology, orthopaedics, paediatrics and sports or no appropriate value.
226 Each trial can be assigned up to three codes for subdiscipline, in our study we will
227 select the most applicable subdiscipline and this will be coded as a dummy variable.
228 Each trial assigned the intervention code “electrotherapy, heat, cold” will be coded
229 as “1”, with the remainder coded as “0”. The language of publication will be coded
230 to produce two different variables: “1” for English and “0” for languages other than
231 English, and Chinese as “0” and all other languages as “1”. The year of publication
232 will be subtracted from 2017 to produce an “age” (in years) for each trial.

233 One reviewer will determine if the trial was registered and if the journal of
234 publication for each trial endorses the CONSORT statement. Registration will be
235 extracted from the full article or, if not reported in the full article, by searching the
236 International Clinical Trials Registry Platform (<http://apps.who.int/trialsearch/>) and
237 will be coded as “1” for “yes” or “0” for “no”. Journal endorsement of the
238 CONSORT statement will be achieved by reviewing the list of journals on the
239 CONSORT web-site³⁶ and, if necessary, visiting journal web-sites and reviewing
240 the instructions for authors and other editorial policies.

241 One reviewer will collect the journal impact factor at the time of pilot trial
242 publication (as a continuous variable) through a search at Journal Citation Reports
243 website (<https://jcr.incites.thomsonreuters.com>). Other variables, including number
244 of authors (as a continuous variable) and sample size (as a continuous variable), will
245 be collected by one reviewer through the electronic data extraction form designed
246 for this review.

247

248 **Statistical analysis**

249 Firstly, we will calculate the number, percentage and 95% confidence

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3 250 interval of trials indexed in PEDro that claim to be a feasibility or pilot trial that
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5 251 evaluate feasibility. The PEDro confidence interval calculator will be used to
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7 252 calculate the 95% confidence interval.³⁷ We will also compute the aspect of
8
9 253 feasibility evaluated in the primary objective(s) of the pilot or feasibility trials.

10
11 254 The primary analysis will be a descriptive analysis of completeness of
12
13 255 reporting of the abstracts and full articles of the pilot or feasibility trials. The
14
15 256 frequency that each item is scored as “Reported”, “Inadequately reported”, “Not
16
17 257 reported” and “Not applicable” for the CONSORT pilot and feasibility trials
18
19 258 checklist and CONSORT pilot and feasibility trials abstracts checklist will be
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21 259 tabulated. The mean (standard deviation) summary score will be calculated for each
22
23 260 checklist.

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26 261 In the secondary analysis, we will perform a Poisson regression analysis to
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28 262 determine which study characteristics are associated with greater completeness
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30 263 reporting. Two independent models will be built, one using the summary score for
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32 264 the CONSORT pilot and feasibility trials checklist (i.e., for the full article) as the
33
34 265 dependent variable and the second model using the summary score for the
35
36 266 CONSORT pilot and feasibility trials abstracts checklist. Independent variables for
37
38 267 both models will be: 1) publication in a journal which endorses CONSORT^{12, 13}
39
40 268 (“1” for “yes” or “0” for “no”) 2) trial funded¹⁴ (“1” for “yes” or “0” for “no”) 3)
41
42 269 sample size¹⁴ (as a continuous variable); 4) reported trial registration number (“1”
43
44 270 for “yes” and “0” for “no”), 5) total PEDro score (continuous variable, 0-10); 6)
45
46 271 most applicable subdiscipline of physiotherapy²⁷ (coded as dummy variables), 6)
47
48 272 language of publication (“1” for English and “0” for all other languages), 7) non-
49
50 273 Chinese reports (“1” for “yes” and “0” for “no”), 8) number of authors (continuous
51
52 274 variable), 9) reporting allocation concealment (PEDro scale item 3; “1” for “yes”
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3 275 and “0” for “no”) and 10) type of intervention (“1” for electrotherapy and “0” for
4
5 276 non-electrotherapy).

6
7 277 We will use Generalised Estimating Equation (GEE) analysis, assuming an
8
9 278 exchangeable correlation structure, to explore factors associated with completeness
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11 279 of reporting. GEE allows us to model possible correlation or similarity of the papers
12
13 280 published within the same journal. All analyses will be performed using SAS 9.2
14
15 281 (Cary, NC).

16 282

17 283 **DISCUSSION**

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20 284 This study will be the first to describe the completeness of reporting of pilot
21
22 285 or feasibility trials for an entire field of healthcare (physiotherapy) using the
23
24 286 CONSORT extension to randomised pilot and feasibility trials. This is important as
25
26 287 good reporting, or transparency, will provide sufficient information about the
27
28 288 methods and results of the trial to guide clinical practice and further research to both
29
30 289 clinicians and researchers.

31
32
33 290 The transparency in reporting randomised controlled trials has improved
34
35 291 since the introduction of the CONSORT statement.¹² A number of other factors are
36
37 292 also associated with better trial quality, including being funded¹⁴, prospectively
38
39 293 registered¹³, published in English¹⁵, and having larger sample sizes.^{14, 29} Whether
40
41 294 these variables are also associated with a better reporting quality of pilot or
42
43 295 feasibility studies has not been rigorously investigated. To the best of our
44
45 296 knowledge, only one study has evaluated quality of reporting of pilot studies⁷. That
46
47 297 study did not use a scale or checklist to evaluate reporting, nor did it test for
48
49 298 possible factors that could predict quality.⁷

1
2
3 299 The results of this study are likely to influence authors, funding agencies,
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5 300 ethics committees, journal editors and peer reviewers to improve the reporting and
6
7 301 review process for pilot and feasibility trials. We expect that our results will provide
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9 302 important baseline data which can be used for comparative purposes in the
10
11 303 evaluation of strategies aimed to improve the reporting and quality of reports of
12
13 304 pilot and feasibility trials.
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17
18 306 **Ethics and dissemination**

19
20 307 This survey does not require ethical approval because it is a methodological
21
22 308 review of published reports of randomised controlled trials. The results of this study
23
24 309 will be disseminated through peer review publication and presentation at
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26 310 international conferences.
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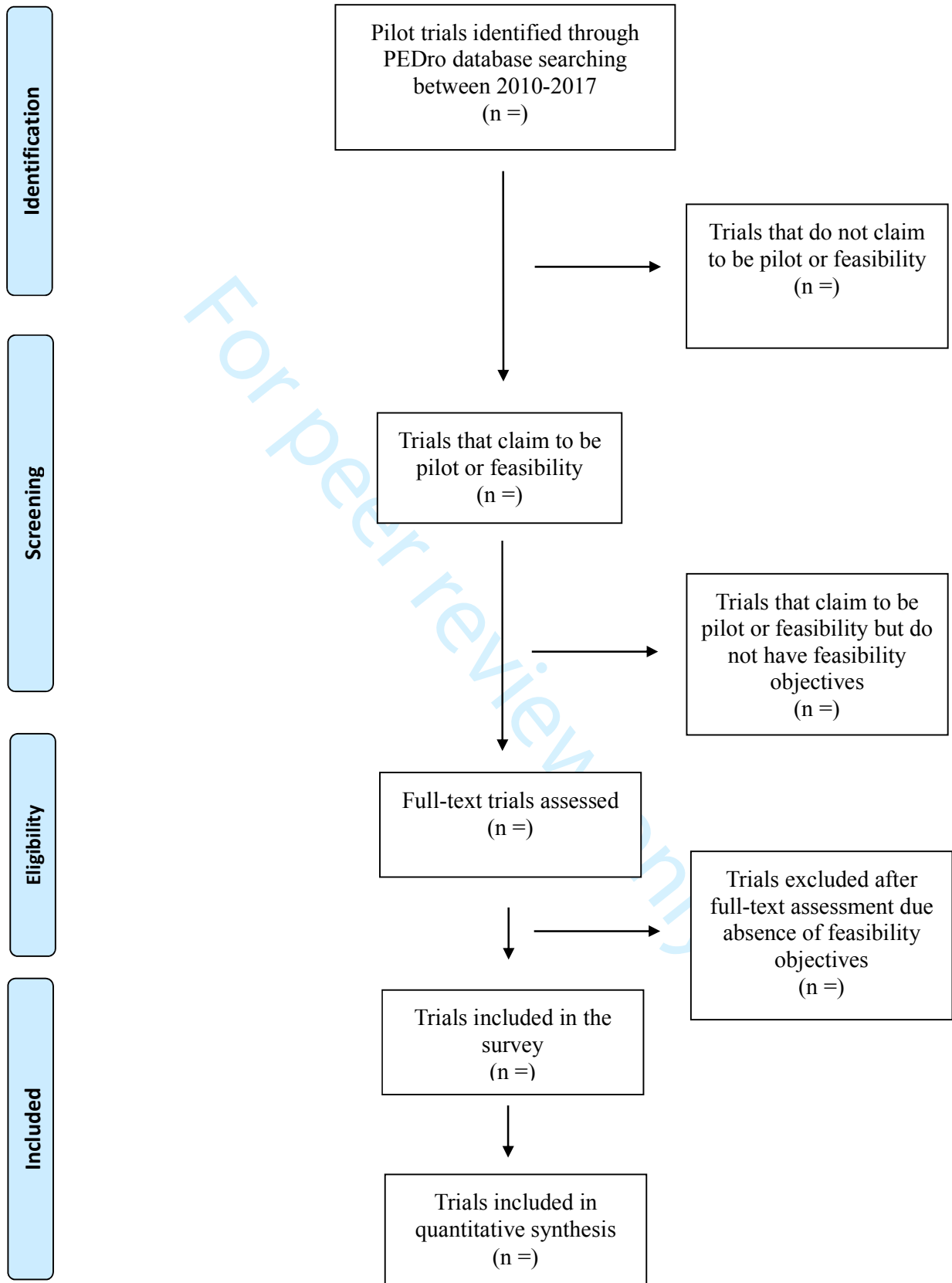
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A METHODOLOGICAL SURVEY ON REPORTING OF PILOT AND FEASIBILITY TRIALS FOR PHYSIOTHERAPY INTERVENTIONS: A STUDY PROTOCOL

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Primary Subject Heading:	Research methods
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Keywords:	Pilot, Clinical trial, Dress rehearsal, Feasibility, Vanguard

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3 1 **A METHODOLOGICAL SURVEY ON REPORTING OF PILOT AND**
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5 2 **FEASIBILITY TRIALS FOR PHYSIOTHERAPY INTERVENTIONS: A**
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7 3 **STUDY PROTOCOL**
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50
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27 **AUTHORS' CONTRIBUTIONS**

28 LFCS wrote the first draft.

29 LFCS, LCMC and MA incorporated comments from authors on successive
30 manuscripts.

31 LT and AM conceptualized the study.

32 All authors contributed to design of the study, reviewed and approved the
33 manuscript.

34 **COMPETING INTEREST**

35 The authors have no conflicts of interest to declare.

37 **ABSTRACT**

38 **Introduction:** Pilot and feasibility trials aim to test whether a full trial can be
39 conducted or if any procedures must be changed for the full trial. Pilot trials must be
40 reported in a transparent, accurate and complete way. In this report, we present a
41 protocol for a methodological survey with the following aims: 1) determine the
42 percentage of Physiotherapy trial reports which claim to be pilot or feasibility trials
43 which evaluate feasibility; 2) determine the aspect of feasibility evaluated in the
44 primary objective(s) of the pilot or feasibility trials; 3) describe the completeness of
45 reporting of abstracts and full articles of pilot or feasibility trials using the
46 CONSORT extension to randomised pilot and feasibility trials, and 4) investigate
47 factors associated with completeness of reporting of pilot or feasibility trials.

48 **Methods and analysis:** Reports of randomised controlled trials indexed in the
49 Physiotherapy Evidence Database (PEDro) that claim to be pilot or feasibility trials

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2
3 50 and published in 2011-2017 will be included. Two independent reviewers will
4
5 51 confirm eligibility and classify the aspect of feasibility being evaluated in the
6
7 52 objective(s) of the included pilot or feasibility trials. Completeness of reporting of
8
9 53 both the abstract and full article will be evaluated using the CONSORT extension to
10
11 54 randomised pilot and feasibility trials. The primary analysis will be a descriptive
12
13 55 analysis about reporting quality of abstracts and full texts of pilot and feasibility
14
15 56 trials. We will use Generalized Estimating Equations (GEE) to explore factors
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17 57 associated with completeness of reporting.

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19 58 **Ethics and dissemination:** The results of this study will be disseminated by
20
21 59 presentation at conferences and will be submitted for publication in a peer reviewed
22
23 60 journal. Ethical approval is not necessary for this study.
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29 61

30 62 **Key words:** Pilot, Feasibility, Vanguard, Dress rehearsal, Clinical trial.

31 63

32 64 **Strengths and limitations of this study**

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36 65 • This study will be the first to evaluate the quality of reporting of abstracts
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38 66 and full articles of pilot or feasibility trials in Physiotherapy field using the
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40 67 CONSORT statement extension for pilot and feasibility studies.
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43 68 • All data will be extracted by two independent reviewers in order to increase
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45 69 precision.
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48 70 • Findings from this study are restricted to pilot and feasibility trials published
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50 71 between 2011-2017 indexed on the Physiotherapy Evidence Database.
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52 72 Therefore, the results of this study cannot be generalised to all existing pilot
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54 73 and feasibility trials.
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75 INTRODUCTION

76 Pilot and feasibility trials are exploratory studies that aim to investigate
77 whether the crucial components of planning or preparing for a larger and definitive
78 randomised controlled trial will be viable.^{1,2} They are intended to provide useful
79 information with regards to planning complex interventions (e.g. identifying the
80 optimal dose, testing safety), testing study procedures (e.g. the form of
81 randomisation, estimation of recruitment rate, plausibility of multicentre
82 collaborations), investigating surrogate outcomes or estimating parameters to help
83 to perform sample size calculation.^{3, 4} Although pilot and feasibility trials have
84 slightly different definitions, both are designed to establish whether the main or
85 definitive trial can and should be conducted in the future, and, if so, to determine
86 how the main trial should be done.⁵ Pilot and feasibility trials are designed to ensure
87 that the main trial will be achievable, rigorous and economically justifiable in order
88 to avoid waste of resources.⁴ However, without a clear understanding of how the
89 pilot or feasibility trial was conducted, researchers and clinicians would not be able
90 to judge the methodological quality and to clinically appraise the published report
91 of the trial.

92 Evaluations of published pilot and feasibility trials suggests that the trials
93 may not actually be evaluating feasibility^{6,7} and are being poorly reported.⁷ In a
94 small sample of 93 pilot and feasibility trials published in Indian biomedical
95 journals, 68% of trials performed between-group statistical comparisons and none
96 reported feasibility objectives⁷. In addition, an ad-hoc list of trial characteristics was
97 used to evaluate reporting, rather than a scale or checklist. Another survey of 191
98 pilot and feasibility trials published in 1987-2015 in a single journal (i.e. *Clinical*
99 *Rehabilitation*)⁶ revealed that 110 (58%) trials actually tested feasibility for a future

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3 100 trial, with only 23 trials being followed by a definitive trial.⁶ This implies that the
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5 101 terms “pilot” or “feasibility” may be being incorrectly used to assist in the
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7 102 publication of small trials rather than to systematically test procedures to inform the
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9 103 conduct of a large definitive trial. Since those evaluations were published, the
10
11 104 methods for evaluating the quality of reporting of pilot and feasibility trials have
12
13 105 improved substantially with the introduction of an extension of the Consolidated
14
15 106 Standards of Reporting Trials (CONSORT) statement specifically for randomised
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17 107 pilot and feasibility trials.^{8,9} This extension consists of a 40-item checklist for full
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19 108 articles and a 16-item checklist for abstracts.

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24 109 The completeness of reporting of full published reports of randomised
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26 110 controlled trials¹⁰⁻¹⁵ and the abstracts of trials¹⁶⁻¹⁸ have been evaluated to be sub-
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28 111 optimal across all areas of healthcare, including in Physiotherapy.^{11, 13-15, 19} Factors
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30 112 which appear to be associated with improved reporting quality or methodological
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32 113 quality include publication in a journal with a high impact factor,²⁰⁻²² being a
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34 114 multicentre trial,^{23, 24, 21, 25} higher number of authors,^{21, 26} publication in a journal
35
36 115 that endorses the CONSORT statement,^{12,13,19} language of publication,^{15,21,25}
37
38 116 discipline of Physiotherapy,²⁷ year of publication,^{13, 28} receiving funding,¹⁴ sample
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40 117 size,^{14, 29} and evidence of clinical trial registration.^{13, 19}

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44 118 The number of randomised controlled trials in Physiotherapy has grown
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46 119 exponentially over time³⁰. Time and funding are resources that could be saved by
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48 120 conducting high-quality pilot and feasibility studies. To our knowledge, the
49
50 121 reporting quality of pilot and feasibility trails of Physiotherapy interventions using
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52 122 the new extension of the CONSORT statement for randomised pilot and feasibility
53
54 123 trials has not yet been performed, nor the factors associated with better reporting
55
56 124 identified.

125 **OBJECTIVES**

126 The purpose of this methodological survey is to describe the quality of
127 reporting of abstracts and full articles of pilot or feasibility trials from a
128 representative sample in the field of Physiotherapy. Specifically, the first aim is to
129 determine the percentage of trial reports indexed in PEDro Database, which claim to
130 be pilot or feasibility trials, which evaluate feasibility. Second, to determine the
131 aspect of feasibility evaluated in the primary objective(s) of the true pilot or
132 feasibility trials. Third, to describe the completeness of reporting of abstracts and
133 full articles using the CONSORT extension for randomised pilot and feasibility
134 trials. Fourth, to investigate factors associated with completeness of reporting of
135 pilot or feasibility trials.

136

137 **METHODS**

138 **Study design**

139 This study is a methodological survey of completeness of reporting of
140 abstracts and full articles of pilot or feasibility trials for Physiotherapy
141 interventions.

142

143 **Eligibility criteria**

144 We will include all reports of randomised controlled trials indexed in the
145 Physiotherapy Evidence Database (PEDro; www.pedro.org.au) that claim to be a
146 pilot or feasibility trial. We will only include trials published in 2011-2017 which
147 are fully indexed in PEDro (in-process trials, which have not had search terms and
148 PEDro scores allocated, will not be included). We decided to only include trials
149 published after 2010 because the International Committee of Medical Journal

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3 150 Editors (ICMJE) stated that all trials started after July 2005 should be registered in a
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5 151 free, publicly available and electronically searchable register^{31, 32} and also because
6
7 152 the last update of the CONSORT statement was published in 2010. There will be no
8
9
10 153 language restrictions.

11
12 154 We selected PEDro database as the source of trial reports because PEDro is
13
14 155 one of the most comprehensive indexes of reports of randomised controlled trials
15
16 156 evaluating Physiotherapy interventions^{33, 34}. Moreover, all trials indexed on PEDro
17
18 157 are rated for methodological quality and the completeness of statistical reporting
19
20 158 using the PEDro scale³⁵ and are coded for the area (or subdiscipline) of
21
22 159 Physiotherapy practice and type of intervention. To be eligible for inclusion on
23
24 160 PEDro, trials must involve comparison of at least two interventions (or an
25
26 161 intervention and control condition) applied to subjects who are representative of
27
28 162 those who the interventions might be applied to in the course of clinical practice,
29
30 163 with at least one of the interventions under evaluation being part of Physiotherapy
31
32 164 practice. In addition, all trials included in PEDro must involve random (or intend-
33
34 165 to-be-random) allocation of subjects into interventions, and be fully published in a
35
36 166 peer-reviewed journal.³⁶

167 168 **Search strategy**

169 To identify reports of pilot or feasibility trials a search on PEDro database
170 will be conducted for the period from 2011 to 2017. We will use “Clinical trial” in
171 the Method field combined with the following search terms in the Abstract & Title
172 field: Pilot* OR Feasibility* OR Vanguard* OR “Dress rehearsal”.

173

174 **Studies selection**

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2
3 175 Two independent reviewers will screen the title and abstracts of the trials in
4
5 176 the search results to identify trials, which claim to be a pilot or feasibility trial. The
6
7 177 title, abstract and, if necessary, full-text of these self-identified pilot or feasibility
8
9 178 trials will be evaluated to identify the sub-set of articles which contain objective(s)
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11 179 linked with feasibility. Any disagreements between reviewers will be resolved by
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13 180 discussion or, if necessary, arbitration by a third reviewer. Figure 1 presents the
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15 181 flow diagram used to guide article selection.
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Insert figure 1 here

186 **Data extraction**

187 Two independent reviewers will classify the reason(s) to conduct a pilot or
188 feasibility for each included trial. There are several reasons for conducting pilot and
189 feasibility studies. These reasons could be grouped under some broad
190 classifications³⁷. A widely known tutorial⁴ aimed to provide a detailed examination
191 of the key aspects of pilot studies suggested four categories to classify the rationale
192 to conduct a pilot study. The four categories are: 1) process (steps that need to take
193 place as part of the main study), 2) resources (time and budget), 3) management
194 (human and data optimization) or 4) scientific (issues like treatment safety).⁴ If
195 more than one category is identified for an included trial, we will code for all
196 relevant categories and indicate which category is linked to the primary objective of
197 the trial. The number of subjects randomised and whether the pilot or feasibility
198 trial recommends that a large-scale trial will be conducted will also be recorded.

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3 199 The two independent reviewers will also complete the CONSORT pilot and
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5 200 feasibility trials checklist (40 items) and the CONSORT pilot and feasibility trials
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8 201 abstracts checklist (16 items; note, the “author” item was omitted as this relates to
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10 202 conference abstracts only) for each trial.^{8,9} The CONSORT checklist include items
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12 203 related to the title, trial design, methods, results, conclusions, registration and
13
14 204 funding. Each item will be rated as “Reported”, “Inadequately reported”, “Not
15
16 205 reported” or “Not Applicable”. Summary scores for the CONSORT pilot and
17
18 206 feasibility trials checklist (range, 0 to 40) and CONSORT pilot and feasibility trials
19
20 207 abstracts checklist (range, 0 to 16) will be calculated by tallying the items scored as
21
22 208 “Reported”.

26 209 The reviewers will independently extract the data using an electronic data
27
28 210 extraction form designed for this survey. The data extraction form will be created
29
30 211 using information from the CONSORT extension to randomised pilot and feasibility
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32 212 trials. We will pilot the data extraction forms on ten randomly selected trials before
33
34 213 proceeding with full data extraction to ensure all reviewers extract data consistently
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36 214 and to ensure the data extraction form is unambiguous and free from errors.
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38 215 Discrepancies between the two reviewers will be resolved by discussion and by
39
40 216 consulting the published explanation of the CONSORT checklists. If necessary,
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42 217 arbitration by a third reviewer will help to provide consensus on the data extracted.
43
44 218 In order to improve the clarity regarding inclusions and exclusions and to increase
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46 219 accuracy and consistency among the reviewers, between reviewer agreements will
47
48 220 be measured using the Kappa coefficients using an initial trial run involving 10
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50 221 articles per reviewer. If adequate reliability will be not achieved, additional training
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52 222 or improvement in the data extraction form will be undertaken.
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3 223 PEDro scale scores, subdiscipline of Physiotherapy, intervention, language
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5 224 of publication and year of publication will be downloaded from PEDro. The PEDro
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8 225 scale is an 11-item scale which methodological quality and completeness of
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10 226 statistical reporting of reports of randomised controlled trials.³⁵ The items are: 1)
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12 227 eligibility criteria and source of subjects; 2) random allocation; 3) concealed
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14 228 allocation; 4) baseline comparability; 5) blinding of subjects; 6) blinding of
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16 229 therapists; 7) blinding of assessors; 8) > 85% follow-up; 9) intention-to-treat
17
18 230 analysis; 10) between-group statistical comparisons; and 11) reporting of point
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20 231 measures and measures of variability.³⁵ Each item is rated as “yes” (unambiguously
21
22 232 achieved) or “no”, with the number of “yes” responses for items 2-11 tallied to give
23
24 233 the total PEDro score (out of 10). Both the individual items (coded as “0” for “no”
25
26 234 or “1” for “yes”) and the total PEDro score (range, 0 to 10) will be downloaded.
27
28 235 There is evidence that PEDro scale has higher reliability for individual ratings and
29
30 236 consensus ratings compared to the Cochrane risk of bias^{35, 38}. Also, PEDro scale is
31
32 237 strongly correlated ($r=0.83$; 95% CI 0.76 to 0.88) with the Cochrane Risk of Bias
33
34 238 scale³⁹. The subdiscipline of Physiotherapy codes are: cardiothoracic, continence
35
36 239 and women’s health, ergonomics and occupational health, gerontology,
37
38 240 musculoskeletal, neurology, oncology, orthopaedics, paediatrics and sports or no
39
40 241 appropriate value. Each trial can be assigned up to three codes for subdiscipline, in
41
42 242 our study we will select the most applicable subdiscipline and this will be coded as
43
44 243 a dummy variable. The language of publication will be coded to produce two
45
46 244 different variables: “1” for English and “0” for languages other than English, and
47
48 245 Chinese as “0” and all other languages as “1”. The year of publication will be
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50 246 subtracted from 2017 to produce an “age” (in years) for each trial.
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3 247 One reviewer will determine if the trial was registered and if the journal of
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5 248 publication for each trial endorses the CONSORT statement. Clinical trial
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7 249 registration will be extracted from the full article or, if not reported in the full article,
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10 250 by searching the International Clinical Trials Registry Platform
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12 251 (<http://apps.who.int/trialsearch/>) and will be coded as “1” for “yes” or “0” for “no”.
13
14 252 Journal endorsement of the CONSORT statement will be achieved by reviewing the
15
16 253 list of journals on the CONSORT web-site⁴⁰ and, if necessary, visiting journal web-
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18 254 sites and reviewing the instructions for authors and other editorial policies.

21 255 One reviewer will collect the journal impact factor at the time of pilot trial
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23 256 publication (as a continuous variable) through a search at Journal Citation Reports
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25 257 website (<https://jcr.incites.thomsonreuters.com>). Other variables, including number
26
27 258 of authors (as a continuous variable), source of funding, declaration of conflict of
28
29 259 interests and sample size (as a continuous variable), will be collected by one
30
31 260 reviewer through the electronic data extraction form designed for this review.
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37 262 **Patient and Public Involvement**

39 263 Patients and or public were not involved on this study.

41 264

43 265 **Statistical analysis**

45 266 Firstly, we will calculate the number, percentage and 95% confidence
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47 267 interval of trials indexed in PEDro that claim to be a feasibility or pilot trial that
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49 268 evaluate feasibility. The PEDro confidence interval calculator will be used to
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51 269 calculate the 95% confidence interval.⁴¹ We will also compute the aspect of
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53 270 feasibility evaluated in the primary objective(s) of the pilot or feasibility trials.

54 271 The primary analysis will be a descriptive analysis of completeness of
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3 272 reporting of the abstracts and full articles of the pilot or feasibility trials. The
4
5 273 frequency that each item is scored as “Reported”, “Inadequately reported”, “Not
6
7
8 274 reported” and “Not applicable” for the CONSORT pilot and feasibility trials
9
10 275 checklist and CONSORT pilot and feasibility trials abstracts checklist will be
11
12 276 tabulated. The mean (standard deviation) summary score will be calculated for each
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14
15 277 checklist.

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17 278 In the secondary analysis, we will perform a Poisson regression analysis to
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19 279 determine which study characteristics are associated with greater completeness
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21 280 reporting. Two independent models will be built, one using the summary score for
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23 281 the CONSORT pilot and feasibility trials checklist (i.e., for the full article) as the
24
25 282 dependent variable and the second model using the summary score for the
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27 283 CONSORT pilot and feasibility trials abstracts checklist. Independent variables for
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29 284 both models will be: 1) publication in a journal which endorses CONSORT^{12, 13}
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31 285 (“1” for “yes” or “0” for “no”) 2) trial funded¹⁴ (“1” for “yes” or “0” for “no”) 3)
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33 286 sample size¹⁴ (as a continuous variable), 4) reported trial registration number (“1”
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35 287 for “yes” and “0” for “no”), 5) total PEDro score (continuous variable, 0-10), 5)
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37 288 most applicable subspecialty of Physiotherapy²⁷ (coded as dummy variables), 6)
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39 289 language of publication (“1” for English and “0” for all other languages), 7) non-
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41 290 Chinese reports (“1” for “yes” and “0” for “trials published in languages other than
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43 291 Chinese”), 8) number of authors (continuous variable), 9) reporting allocation
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45 292 concealment (PEDro scale item 3, “1” for “yes” and “0” for “no”).

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47 293 We will use Generalised Estimating Equation (GEE) analysis, assuming an
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49 294 exchangeable correlation structure, to explore factors associated with completeness
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51 295 of reporting. GEE allows us to model possible correlation or similarity of the papers
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53 296 published within the same journal. All analyses will be performed using SAS 9.2
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8 299 **DISCUSSION**
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10 300 This study will be the first to describe the completeness of reporting of pilot
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12 301 or feasibility trials from a representative sample on the field of Physiotherapy using
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14 302 the CONSORT extension to randomised pilot and feasibility trials. This is important
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16 303 as good reporting, or transparency, will provide sufficient information about the
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18 304 methods and results of the trial to guide clinical practice and further research to both
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20 305 clinicians and researchers.
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23 306 The transparency in reporting randomised controlled trials has improved
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25 307 since the introduction of the CONSORT statement.¹² A number of other factors are
26
27 308 also associated with better trial quality, including being funded¹⁴, prospectively
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29 309 registered¹³, published in English¹⁵, and having larger sample sizes.^{14, 29} Whether
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31 310 these variables are also associated with a better reporting quality of pilot or
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33 311 feasibility studies has not been rigorously investigated. To the best of our
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35 312 knowledge, only one study has evaluated quality of reporting of pilot studies⁷. That
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37 313 study did not use a scale or checklist to evaluate reporting, nor did it test for
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39 314 possible factors that could predict quality.⁷
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47 316 **Ethics and dissemination**
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49 317 This survey does not require ethical approval because it is a methodological
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51 318 review of published reports of randomised controlled trials. The results of this study
52
53 319 will be disseminated through peer review publication and presentation at
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55 320 international conferences.
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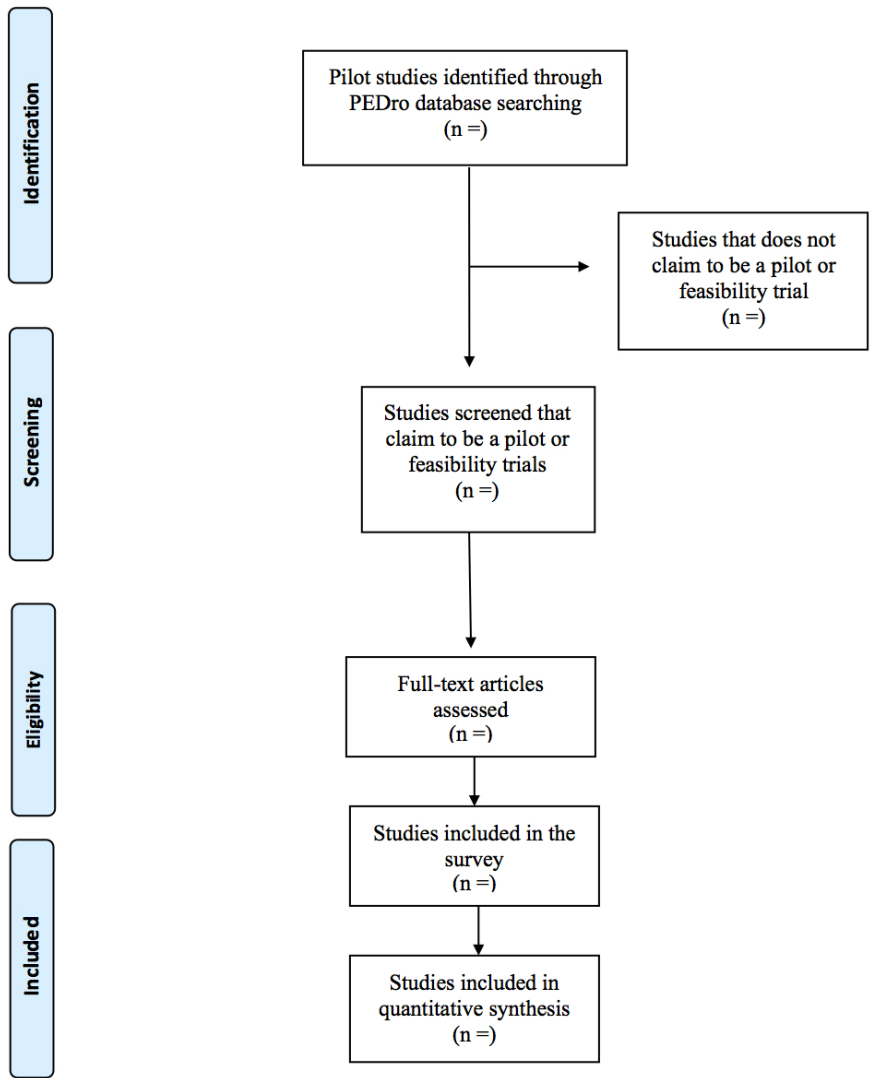


Figure 1: Study flow diagram

BMJ Open

A METHODOLOGICAL SURVEY ON REPORTING OF PILOT AND FEASIBILITY TRIALS FOR PHYSIOTHERAPY INTERVENTIONS: A STUDY PROTOCOL

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2017-020580.R2
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Primary Subject Heading:	Research methods
Secondary Subject Heading:	Evidence based practice, Rehabilitation medicine
Keywords:	Pilot, Clinical trial, Dress rehearsal, Feasibility, Vanguard

SCHOLARONE™
Manuscripts

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3 1 **A METHODOLOGICAL SURVEY ON REPORTING OF PILOT AND**
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5 2 **FEASIBILITY TRIALS FOR PHYSIOTHERAPY INTERVENTIONS: A**
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7 3 **STUDY PROTOCOL**
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12 5 Luiz Felicio Cadete Scola¹, Anne Moseley², Lehana Thabane^{3,4}, Matheus Almeida¹,
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49 21 **FUNDING STATEMENT**

50
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52
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54
55 24 Education Personnel (CAPES), Brazil. Mr. Almeida has his Post-Doctoral
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27 **AUTHORS' CONTRIBUTIONS**

28 LFCS wrote the first draft.

29 LFCS, LCMC and MA incorporated comments from authors on successive
30 manuscripts.

31 LT and AM conceptualized the study.

32 All authors contributed to design of the study, reviewed and approved the
33 manuscript.

34 **COMPETING INTEREST**

35 The authors have no conflicts of interest to declare.

37 **ABSTRACT**

38 **Introduction:** Pilot and feasibility trials aim to test whether a full trial can be
39 conducted or if any procedures must be changed for the full trial. Pilot trials must be
40 reported in a transparent, accurate and complete way. In this report, we present a
41 protocol for a methodological survey with the following aims: 1) determine the
42 percentage of Physiotherapy trial reports which claim to be pilot or feasibility trials
43 which evaluate feasibility, 2) determine the aspect of feasibility evaluated in the
44 primary objective(s) of the pilot or feasibility trials, 3) describe the completeness of
45 reporting of abstracts and full articles of pilot or feasibility trials using the
46 CONSORT extension to randomised pilot and feasibility trials, and 4) investigate
47 factors associated with completeness of reporting of pilot or feasibility trials.

48 **Methods and analysis:** Reports of randomised controlled trials indexed in the
49 Physiotherapy Evidence Database (PEDro) that claim to be pilot or feasibility trials

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3 50 and published in 2011-2017 will be included. Two independent reviewers will
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5 51 confirm eligibility and classify the aspect of feasibility being evaluated in the
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7 52 objective(s) of the included pilot or feasibility trials. Completeness of reporting of
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9 53 both the abstract and full article will be evaluated using the CONSORT extension to
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11 54 randomised pilot and feasibility trials. The primary analysis will be a descriptive
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13 55 analysis about reporting quality of abstracts and full texts of pilot and feasibility
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15 56 trials. We will use Generalized Estimating Equations (GEE) to explore factors
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17 57 associated with completeness of reporting.
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21 58 **Ethics and dissemination:** The results of this study will be disseminated by
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23 59 presentation at conferences and will be submitted for publication in a peer reviewed
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25 60 journal. Ethical approval is not necessary for this study.
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29 61

30 62 **Key words:** Pilot, Feasibility, Vanguard, Dress rehearsal, Clinical trial.
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35 64 **Strengths and limitations of this study**

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37 65 • This study will be the first to evaluate the quality of reporting of abstracts
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39 66 and full articles of pilot or feasibility trials in Physiotherapy field using the
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41 67 CONSORT statement extension for pilot and feasibility studies.
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43 68 • All data will be extracted by two independent reviewers in order to increase
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45 69 precision.
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47 70 • Findings from this study are restricted to pilot and feasibility trials published
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49 71 between 2011-2017 indexed on the Physiotherapy Evidence Database.
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51 72 Therefore, the results of this study cannot be generalised to all existing pilot
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53 73 and feasibility trials in physiotherapy.
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75 INTRODUCTION

76 Pilot and feasibility trials are exploratory studies that aim to investigate
77 whether the crucial components of planning or preparing for a larger and definitive
78 randomised controlled trial will be viable.^{1,2} They are intended to provide useful
79 information with regards to planning complex interventions (e.g. identifying the
80 optimal dose, testing safety), testing study procedures (e.g. the form of
81 randomisation, estimation of recruitment rate, plausibility of multicentre
82 collaborations), investigating surrogate outcomes or estimating parameters to help
83 to perform sample size calculation.^{3, 4} Although pilot and feasibility trials have
84 slightly different definitions, both are designed to establish whether the main or
85 definitive trial can and should be conducted in the future, and, if so, to determine
86 how the main trial should be done.⁵ Pilot and feasibility trials are designed to ensure
87 that the main trial will be achievable, rigorous and economically justifiable in order
88 to avoid waste of resources.⁴ However, without a clear understanding of how the
89 pilot or feasibility trial was conducted, researchers and clinicians would not be able
90 to judge the methodological quality and to clinically appraise the published report
91 of the trial.

92 Evaluations of published pilot and feasibility trials suggests that the trials
93 may not actually be evaluating feasibility^{6,7} and are being poorly reported.⁷ In a
94 small sample of 93 pilot and feasibility trials published in Indian biomedical
95 journals, 68% of trials performed between-group statistical comparisons and none
96 reported feasibility objectives⁷. In addition, an ad-hoc list of trial characteristics was
97 used to evaluate reporting, rather than a scale or checklist. Another survey of 191
98 pilot and feasibility trials published in 1987-2015 in a single journal (i.e. *Clinical*
99 *Rehabilitation*)⁶ revealed that 110 (58%) trials actually tested feasibility for a future

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3 100 trial, with only 23 trials being followed by a definitive trial.⁶ This implies that the
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5 101 terms “pilot” or “feasibility” may be being incorrectly used to assist in the
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7 102 publication of small trials rather than to systematically test procedures to inform the
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9 103 conduct of a large definitive trial. Since those evaluations were published, the
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11 104 methods for evaluating the quality of reporting of pilot and feasibility trials have
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13 105 improved substantially with the introduction of an extension of the Consolidated
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15 106 Standards of Reporting Trials (CONSORT) statement specifically for randomised
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17 107 pilot and feasibility trials.^{8,9} This extension consists of a 40-item checklist for full
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19 108 articles and a 16-item checklist for abstracts.

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24 109 The completeness of reporting of full published reports of randomised
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26 110 controlled trials¹⁰⁻¹⁵ and the abstracts of trials¹⁶⁻¹⁸ have been evaluated to be sub-
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28 111 optimal across all areas of healthcare, including in Physiotherapy.^{11, 13-15, 19} Factors
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30 112 which appear to be associated with improved reporting quality or methodological
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32 113 quality include publication in a journal with a high impact factor,²⁰⁻²² being a
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34 114 multicentre trial,^{23, 24, 21, 25} higher number of authors,^{21, 26} publication in a journal
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36 115 that endorses the CONSORT statement,^{12,13,19} language of publication,^{15,21,25}
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38 116 discipline of Physiotherapy,²⁷ year of publication,^{13, 28} receiving grants from
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40 117 research funding agencies,¹⁴ sample size,^{14, 29} and evidence of clinical trial
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42 118 registration.^{13, 19}

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47 119 The number of randomised controlled trials in Physiotherapy has grown
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49 120 exponentially over time³⁰. Time and funding are resources that could be saved by
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51 121 conducting high-quality pilot and feasibility studies. To our knowledge, the
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53 122 reporting quality of pilot and feasibility trails of Physiotherapy interventions using
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55 123 the new extension of the CONSORT statement for randomised pilot and feasibility
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3 124 trials has not yet been performed, nor the factors associated with better reporting
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5 125 identified.

6 7 8 126 **OBJECTIVES**

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10 127 The purpose of this methodological survey is to describe the quality of
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12 128 reporting of abstracts and full articles of pilot or feasibility trials from a
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14 129 representative sample in the field of Physiotherapy. Specifically, the first aim is to
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16 130 determine the percentage of trial reports indexed in PEDro Database, which claim to
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18 131 be pilot or feasibility trials, which evaluate feasibility. Second, to determine the
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20 132 aspect of feasibility evaluated in the primary objective(s) of the true pilot or
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22 133 feasibility trials. Third, to describe the completeness of reporting of abstracts and
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24 134 full articles using the CONSORT extension for randomised pilot and feasibility
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26 135 trials. Fourth, to investigate factors associated with completeness of reporting of
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28 136 pilot or feasibility trials.

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34 35 138 **METHODS**

36 37 139 **Study design**

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48 49 144 **Eligibility criteria**

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51 145 We will include all reports of randomised controlled trials indexed in the
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53 146 Physiotherapy Evidence Database (PEDro: www.pedro.org.au) that claim to be a
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55 147 pilot or feasibility trial. We will only include trials published in 2011-2017 which
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57 148 are fully indexed in PEDro (in-process trials, which have not had search terms and
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3 149 PEDro scores allocated, will not be included). We decided to only include trials
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5 150 published after 2010 because the International Committee of Medical Journal
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7 151 Editors (ICMJE) stated that all trials started after July 2005 should be registered in a
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10 152 free, publicly available and electronically searchable register^{31, 32} and also because
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12 153 the last update of the CONSORT statement was published in 2010. There will be no
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15 154 language restrictions.

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17 155 We selected PEDro database as the source of trial reports because PEDro is
18
19 156 one of the most comprehensive indexes of reports of randomised controlled trials
20
21 157 evaluating Physiotherapy interventions^{33, 34}. Moreover, all trials indexed on PEDro
22
23 158 are rated for methodological quality and the completeness of statistical reporting
24
25 159 using the PEDro scale³⁵ and are coded for the area (or subdiscipline) of
26
27 160 Physiotherapy practice and type of intervention. To be eligible for inclusion on
28
29 161 PEDro, trials must involve comparison of at least two interventions (or an
30
31 162 intervention and control condition) applied to subjects who are representative of
32
33 163 those who the interventions might be applied to in the course of clinical practice,
34
35 164 with at least one of the interventions under evaluation being part of Physiotherapy
36
37 165 practice. In addition, all trials included in PEDro must involve random (or intend-
38
39 166 to-be-random) allocation of subjects into interventions, and be fully published in a
40
41 167 peer-reviewed journal.³⁶
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169 **Search strategy**

50
51 170 To identify reports of pilot or feasibility trials a search on PEDro database
52
53 171 will be conducted for the period from 2011 to 2017. We will use “Clinical trial” in
54
55 172 the Method field combined with the following search terms in the Abstract & Title
56
57 173 field: Pilot* OR Feasibility* OR Vanguard* OR “Dress rehearsal”.

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5 175 **Study selection**
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7
8 176 Two independent reviewers will screen titles and abstracts to identify
9
10 177 references that claim to be a pilot or feasibility trial. The title, abstract and, if
11
12 178 necessary, full-text of these self-identified pilot or feasibility trials will be evaluated
13
14 179 to identify the sub-set of articles which contain objective(s) linked with feasibility.
15
16 180 Any disagreements between reviewers will be resolved by discussion or, if
17
18 181 necessary, arbitration by a third reviewer. Figure 1 presents the flow diagram used
19
20 182 to guide article selection.
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Insert figure 1 here

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33 187 **Data extraction**
34

35 188 Two independent reviewers will classify the reason(s) to conduct a pilot or
36
37 189 feasibility for each included trial. There are several reasons for conducting pilot and
38
39 190 feasibility studies. These reasons could be grouped under some broad
40
41 191 classifications³⁷. A widely known tutorial⁴ aimed to provide a detailed examination
42
43 192 of the key aspects of pilot studies suggested four categories to classify the rationale
44
45 193 to conduct a pilot study. The four categories are: 1) process (steps that need to take
46
47 194 place as part of the main study), 2) resources (time and budget), 3) management
48
49 195 (human and data optimization) or 4) scientific (issues like treatment safety).⁴ If
50
51 196 more than one category is identified for an included trial, we will code for all
52
53 197 relevant categories and indicate which category is linked to the primary objective of
54
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3 198 the trial. The number of subjects randomised and whether the pilot or feasibility
4
5 199 trial recommends that a large-scale trial will be conducted will also be recorded.
6
7

8 200 The two independent reviewers will also complete the CONSORT pilot and
9
10 201 feasibility trials checklist (40 items) and the CONSORT pilot and feasibility trials
11
12 202 abstracts checklist (16 items) (note, the “author” item was omitted as this relates to
13
14 203 conference abstracts only) for each trial.^{8,9} The CONSORT checklist include items
15
16 204 related to the title, trial design, methods, results, conclusions, registration and
17
18 205 funding. Each item will be rated as “Reported”, “Inadequately reported”, “Not
19
20 206 reported” or “Not Applicable”. Summary scores for the CONSORT pilot and
21
22 207 feasibility trials checklist (range, 0 to 40) and CONSORT pilot and feasibility trials
23
24 208 abstracts checklist (range, 0 to 16) will be calculated by tallying the items scored as
25
26 209 “Reported”.
27
28
29

30 210 The reviewers will independently extract the data using an electronic data
31
32 211 extraction form designed for this survey. The data extraction form will be created
33
34 212 using information from the CONSORT extension to randomised pilot and feasibility
35
36 213 trials. We will pilot the data extraction forms on ten randomly selected trials before
37
38 214 proceeding with full data extraction to ensure all reviewers extract data consistently
39
40 215 and to ensure the data extraction form is unambiguous and free from errors.
41
42 216 Discrepancies between the two reviewers will be resolved by discussion and by
43
44 217 consulting the published explanation of the CONSORT checklists. If necessary,
45
46 218 arbitration by a third reviewer will help to provide consensus on the data extracted.
47
48 219 In order to improve the clarity regarding inclusions and exclusions and to increase
49
50 220 accuracy and consistency among the reviewers, between reviewer agreements will
51
52 221 be measured using the Kappa coefficients using an initial trial run involving 10
53
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3 222 articles per reviewer. If adequate reliability will be not achieved, additional training
4
5 223 or improvement in the data extraction form will be undertaken.
6
7

8 224 PEDro scale scores, subsdiscipline of Physiotherapy, intervention, language
9
10 225 of publication and year of publication will be downloaded from PEDro. The PEDro
11
12 226 scale is an 11-item scale which methodological quality and completeness of
13
14 227 statistical reporting of reports of randomised controlled trials.³⁵ The items are: 1)
15
16 228 eligibility criteria and source of subjects, 2) random allocation, 3) concealed
17
18 229 allocation, 4) baseline comparability, 5) blinding of subjects, 6) blinding of
19
20 230 therapists, 7) blinding of assessors, 8) > 85% follow-up, 9) intention-to-treat
21
22 231 analysis, 10) between-group statistical comparisons, and 11) reporting of point
23
24 232 measures and measures of variability.³⁵ Each item is rated as “yes” (unambiguously
25
26 233 achieved) or “no”, with the number of “yes” responses for items 2-11 tallied to give
27
28 234 the total PEDro score (out of 10). Both the individual items (coded as “0” for “no”
29
30 235 or “1” for “yes”) and the total PEDro score (range, 0 to 10) will be downloaded.
31
32 236 There is evidence that PEDro scale has higher reliability for individual ratings and
33
34 237 consensus ratings compared to the Cochrane risk of bias^{35, 38}. Also, PEDro scale is
35
36 238 strongly correlated ($r=0.83$, 95% CI 0.76 to 0.88) with the Cochrane Risk of Bias
37
38 239 scale³⁹. On the other hand, a meta-epidemiological study found discrepancies in
39
40 240 terms of clinical trial’s quality using PEDro and Cochrane Risk of Bias scale⁴⁰. The
41
42 241 subsdiscipline of Physiotherapy codes are: cardiothoracic, continence and women’s
43
44 242 health, ergonomics and occupational health, gerontology, musculoskeletal,
45
46 243 neurology, oncology, orthopaedics, paediatrics and sports or no appropriate value.
47
48 244 Each trial can be assigned up to three codes for subsdiscipline, in our study we will
49
50 245 select the most applicable subsdiscipline and this will be coded as a dummy variable.
51
52 246 The language of publication will be coded to produce two different variables: “1”
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3 247 for English and “0” for languages other than English, and Chinese as “0” and all
4
5 248 other languages as “1”. The year of publication will be subtracted from 2017 to
6
7 249 produce an “age” (in years) for each trial.
8
9

10 250 One reviewer will determine if the trial was registered and if the journal of
11
12 251 publication for each trial endorses the CONSORT statement. Clinical trial
13
14 252 registration will be extracted from the full article or, if not reported in the full article,
15
16 253 by searching the International Clinical Trials Registry Platform
17
18 254 (<http://apps.who.int/trialsearch/>) and will be coded as “1” for “yes” or “0” for “no”.
19
20 255 Journal endorsement of the CONSORT statement will be achieved by reviewing the
21
22 256 list of journals on the CONSORT web-site⁴¹ and, if necessary, visiting journal web-
23
24 257 sites and reviewing the instructions for authors and other editorial policies.
25
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28 258 One reviewer will collect the journal impact factor if available at the time of
29
30 259 pilot trial publication (as a continuous variable) through a search at Journal Citation
31
32 260 Reports website (<https://jcr.incites.thomsonreuters.com>). Other variables, including
33
34 261 number of authors (as a continuous variable), source of funding, declaration of
35
36 262 conflict of interests and sample size (as a continuous variable), will be collected by
37
38 263 one reviewer through the electronic data extraction form designed for this review.
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43 265 **Patient and Public Involvement**

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46 266 Patients and or public were not involved on this study.
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50 268 **Statistical analysis**

51
52 269 Firstly, we will calculate the number, percentage and 95% confidence
53
54 270 interval of trials indexed in PEDro that claim to be a feasibility or pilot trial that
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56 271 evaluate feasibility. The PEDro confidence interval calculator will be used to
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3 272 calculate the 95% confidence interval.⁴² We will also compute the aspect of
4
5 273 feasibility evaluated in the primary objective(s) of the pilot or feasibility trials.
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7

8 274 The primary analysis will be a descriptive analysis of completeness of
9
10 275 reporting of the abstracts and full articles of the pilot or feasibility trials. The
11
12 276 frequency that each item is scored as “Reported”, “Inadequately reported”, “Not
13
14 277 reported” and “Not applicable” for the CONSORT pilot and feasibility trials
15
16 278 checklist and CONSORT pilot and feasibility trials abstracts checklist will be
17
18 279 tabulated. The mean (standard deviation) summary score will be calculated for each
19
20 280 checklist.
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24 281 In the secondary analysis, we will perform a Poisson regression analysis to
25
26 282 determine which study characteristics are associated with greater completeness
27
28 283 reporting. Two independent models will be built, one using the summary score for
29
30 284 the CONSORT pilot and feasibility trials checklist (i.e., for the full article) as the
31
32 285 dependent variable and the second model using the summary score for the
33
34 286 CONSORT pilot and feasibility trials abstracts checklist. Independent variables for
35
36 287 both models will be: 1) publication in a journal which endorses CONSORT^{12, 13}
37
38 288 (“1” for “yes” or “0” for “no”) 2) trial funded¹⁴ (“1” for “yes” or “0” for “no”) 3)
39
40 289 sample size¹⁴ (as a continuous variable), 4) reported trial registration number (“1”
41
42 290 for “yes” and “0” for “no”), 5) total PEDro score (continuous variable, 0-10), 5)
43
44 291 most applicable subdiscipline of Physiotherapy²⁷ (coded as dummy variables), 6)
45
46 292 language of publication (“1” for English and “0” for all other languages), 7) non-
47
48 293 Chinese reports (“1” for “yes” and “0” for “trials published in languages other than
49
50 294 Chinese”), 8) number of authors (continuous variable), 9) reporting allocation
51
52 295 concealment (PEDro scale item 3, “1” for “yes” and “0” for “no”).
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58 296 We will use Generalised Estimating Equation (GEE) analysis, assuming an
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3 297 exchangeable correlation structure, to explore factors associated with completeness
4
5 298 of reporting. GEE allows us to model possible correlation or similarity of the papers
6
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8 299 published within the same journal. All analyses will be performed using SAS 9.2
9
10 300 (Cary, NC).

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13 14 302 **DISCUSSION**

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17 303 This study will be the first to describe the completeness of reporting of pilot
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19 304 or feasibility trials from a representative sample on the field of Physiotherapy using
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21 305 the CONSORT extension to randomised pilot and feasibility trials. This is important
22
23 306 as good reporting, or transparency, will provide sufficient information about the
24
25 307 methods and results of the trial to guide clinical practice and further research to both
26
27 308 clinicians and researchers.

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29
30 309 The transparency in reporting randomised controlled trials has improved
31
32 310 since the introduction of the CONSORT statement.¹² A number of other factors are
33
34 311 also associated with better trial quality, including being funded¹⁴, prospectively
35
36 312 registered¹³, published in English¹⁵, and having larger sample sizes.^{14, 29} Whether
37
38 313 these variables are also associated with a better reporting quality of pilot or
39
40 314 feasibility studies has not been rigorously investigated. To the best of our
41
42 315 knowledge, only one study has evaluated quality of reporting of pilot studies⁷. That
43
44 316 study did not use a scale or checklist to evaluate reporting, nor did it test for
45
46 317 possible factors that could predict quality.⁷

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49 319 **Ethics and dissemination**

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52 320 This survey does not require ethical approval because it is a methodological
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54 321 review of published reports of randomised controlled trials. The results of this study
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3 322 will be disseminated through peer review publication and presentation at
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5 323 international conferences.
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Figure 1: Study flow diagram

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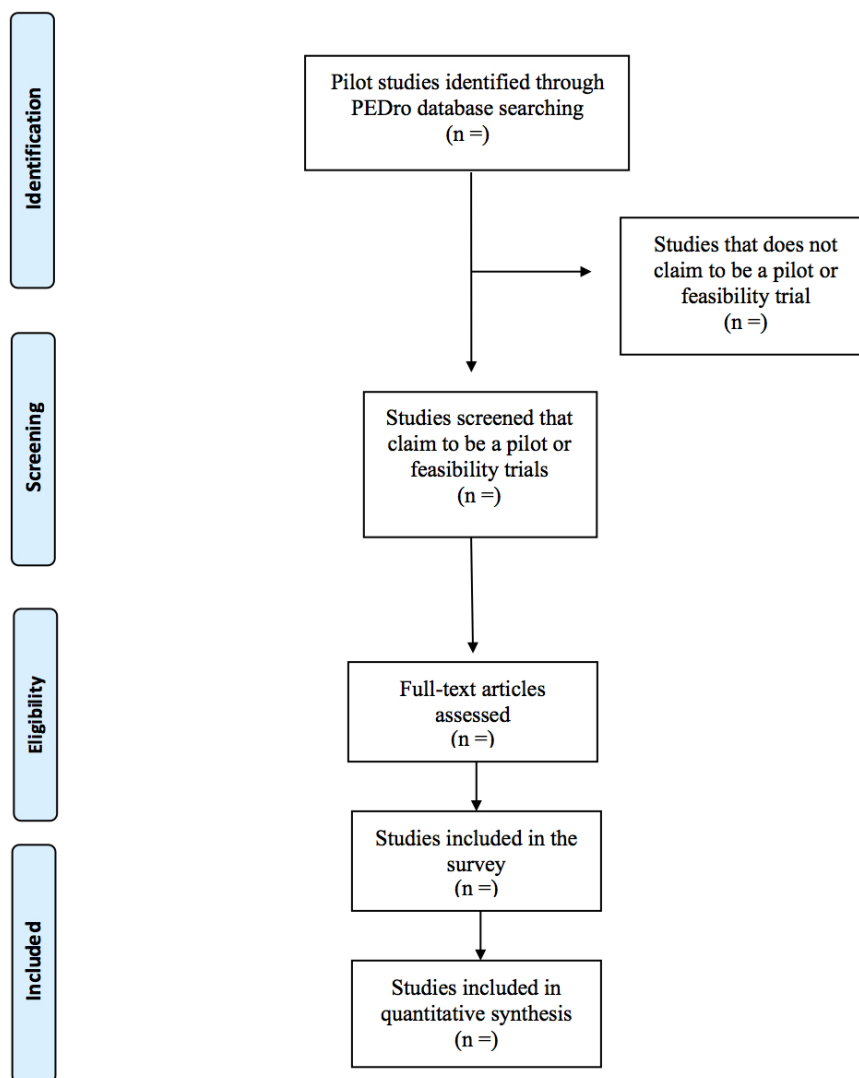


Figure 1: Study flow diagram

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