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

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Keywords:	pilot, feasibility, vanguard, dress rehearsal, clinical trial

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1 1 **A METHODOLOGICAL SURVEY ON REPORTING OF PILOT AND**
2 2 **FEASIBILITY TRIALS FOR PHYSIOTHERAPY INTERVENTIONS: A**
3 3 **STUDY PROTOCOL**

4
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AUTHORS' CONTRIBUTIONS

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

COMPETING INTEREST

The authors have no conflicts of interest to declare.

ABSTRACT

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

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

objective(s) of the included pilot or feasibility trials. Completeness of reporting of both the abstract and full article will be evaluated using the CONSORT extension to randomised pilot and feasibility trials. The primary analysis will be a descriptive analysis about reporting quality of abstracts and full texts of pilot and feasibility trials. We will use Generalized Estimating Equations (GEE) to explore factors associated with completeness of reporting.

Ethics and dissemination: The results of this study will be disseminated by presentation at conferences and will be submitted for publication in a peer reviewed journal. Ethical approval is not necessary for this study.

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

Strengths and limitations of this study

- The results from this study will help improve the transparency in reporting pilot and feasibility trials, allowing clinicians and readers to better understand findings of this type of trials.
- This study will be the first to evaluate the quality of reporting of abstracts and full articles of pilot or feasibility trials for an entire health discipline (physiotherapy).
- The findings of this study are likely to provide guidance for authors, journal editors and peer reviewers on how to report and review pilot and feasibility trials.
- Findings from the present study are restricted to physiotherapy pilot or feasibility trials, so our results may not be generalisable to other areas of healthcare.

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

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

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

To our knowledge, the reporting quality of pilot and feasibility trails of interventions using the new extension of the CONSORT statement for randomised pilot and feasibility trials has not yet been performed for an entire discipline of healthcare, nor the factors associated with better reporting identified.

123

124 **OBJECTIVES**

125 The purpose of this methodological survey is to describe the quality of

126 reporting of abstracts and full articles of pilot or feasibility trials for an entire health
127 discipline (physiotherapy). Specifically, the first aim is to determine the percentage of
128 trial reports which claim to be pilot or feasibility trials which evaluate feasibility.
129 Second, to determine the aspect of feasibility evaluated in the primary objective(s)
130 of the true pilot or feasibility trials. Third, to describe the completeness of reporting
131 of abstracts and full articles using the CONSORT extension for randomised pilot
132 and feasibility trials. Fourth, to investigate factors associated with completeness of
133 reporting of pilot or feasibility trials.

134

135 **METHODS**

136 **Study design**

137 This study is a methodological survey of completeness of reporting of
138 abstracts and full articles of pilot or feasibility trials for physiotherapy interventions.

139

140 **Eligibility criteria**

141 We will include all reports of randomised controlled trials indexed in the
142 Physiotherapy Evidence Database (PEDro; www.pedro.org.au) that claim to be a
143 pilot or feasibility trial. We will only include trials published in 2011-2017 which
144 are fully indexed in PEDro (in-process trials, which have not had search terms and
145 PEDro scores allocated, will not be included). We decided to only include trials
146 published after 2010 because the International Committee of Medical Journal
147 Editors (ICMJE) stated that all trials started after July 2005 should be registered in a
148 free, publicly available and electronically searchable register^{30, 31} and also because
149 the CONSORT statement was first published in 2010. There will be no language
150 restrictions.

151 We selected the PEDro database as the source of trial reports because it is
152 one of the most comprehensive indexes of reports of randomised controlled trials
153 evaluating physiotherapy interventions^{32, 33} plus nearly all trials indexed are rated
154 for methodological quality and the completeness of statistical reporting using the
155 PEDro scale³⁴ and are coded for the area (or subdiscipline) of physiotherapy
156 practice and type of intervention. To be eligible for inclusion on PEDro, trials must
157 involve comparison of at least two interventions (or an intervention and control
158 condition) applied to subjects who are representative of those who the interventions
159 might be applied to in the course of clinical practice, with at least one of the
160 interventions under evaluation being part of physiotherapy practice. In addition, all
161 trials included in PEDro must involve random (or intend-to-be-random) allocation
162 of subjects into interventions, and be fully published in a peer-reviewed journal.³⁵

163
164 **Search strategy**

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

169
170 **Studies selection**

171 Two independent reviewers will screen the title and abstracts of the trials in
172 the search results to identify trials which claim to be a pilot or feasibility trial. The
173 title, abstract and, if necessary, full-text of these self-identified pilot or feasibility
174 trials will be evaluated to identify the sub-set of articles which contain objective(s)

175 linked with feasibility. Any disagreements between reviewers will be resolved by
176 discussion or, if necessary, arbitration by a third reviewer.

177 Figure 1 presents the flow diagram used to guide article selection.

178 *Insert figure 1 here*

180 **Data extraction**

181 Two independent reviewers will classify the pilot or feasibility objective(s)
182 for each included trial. The four categories will be: 1) process (steps that need to
183 take place as part of the main study), 2) resources (time and budget), 3)
184 management (human and data optimization) or 4) scientific (issues like treatment
185 safety).⁴ If more than one category is identified for an included trial, we will code
186 for all relevant categories and indicate which category is linked to the primary
187 objective of the trial. The number of subjects randomised and whether the pilot or
188 feasibility trial recommends that a large-scale trial will be conducted will also be
189 recorded.

190 The two independent reviewers will also complete the CONSORT pilot and
191 feasibility trials checklist (40 items) and the CONSORT pilot and feasibility trials
192 abstracts checklist (16 items; note, the “author” item was omitted as this relates to
193 conference abstracts only) for each trial.^{8,9} The CONSORT checklists include items
194 related to the title, trial design, methods, results, conclusions, registration and
195 funding. Each item will be rated as “Reported”, “Inadequately reported”, “Not
196 reported” or “Not Applicable”. Summary scores for the CONSORT pilot and
197 feasibility trials checklist (range, 0 to 40) and CONSORT pilot and feasibility trials
198 abstracts checklist (range, 0 to 16) will be calculated by tallying the items scored as
199 “Reported”.

200 The reviewers will independently extract the data using an electronic data
201 extraction form designed for this survey. The data extraction form will be created
202 using information from the CONSORT extension to randomised pilot and feasibility
203 trials. We will pilot the data extraction forms on ten randomly selected trials before
204 proceeding with full data extraction to ensure all reviewers extract data consistently
205 and to ensure the data extraction form is unambiguous and free from errors.
206 Discrepancies between the two reviewers will be resolved by discussion and by
207 consulting the published explanation of the CONSORT checklists. If necessary,
208 arbitration by a third reviewer will help provide consensus on the data extracted.
209 Kappa coefficients will be calculated for each stage of screening and data collection
210 to determine the agreement between the independent reviewers.

211 PEDro scale scores, subdiscipline of physiotherapy, intervention, language
212 of publication and year of publication will be downloaded from PEDro. The PEDro
213 scale is an 11-item scale which methodological quality and completeness of
214 statistical reporting of reports of randomised controlled trials.³⁴ The items are: 1)
215 eligibility criteria and source of subjects; 2) random allocation; 3) concealed
216 allocation; 4) baseline comparability; 5) blinding of subjects; 6) blinding of
217 therapists; 7) blinding of assessors; 8) > 85% follow-up; 9) intention-to-treat
218 analysis; 10) between-group statistical comparisons; and 11) reporting of point
219 measures and measures of variability.³⁴ Each item is rated as “yes” (unambiguously
220 achieved) or “no”, with the number of “yes” responses for items 2-11 tallied to give
221 the total PEDro score (out of 10). Both the individual items (coded as “0” for “no”
222 or “1” for “yes”) and the total PEDro score (range, 0 to 10) will be downloaded.
223 The subdiscipline of physiotherapy codes are: cardiothoracic, continence and
224 women’s health, ergonomics and occupational health, gerontology, musculoskeletal,

neurology, oncology, orthopaedics, paediatrics and sports or no appropriate value. Each trial can be assigned up to three codes for subdiscipline, in our study we will select the most applicable subdiscipline and this will be coded as a dummy variable. Each trial assigned the intervention code “electrotherapy, heat, cold” will be coded as “1”, with the remainder coded as “0”. The language of publication will be coded to produce two different variables: “1” for English and “0” for languages other than English, and Chinese as “0” and all other languages as “1”. The year of publication will be subtracted from 2017 to produce an “age” (in years) for each trial.

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

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

247

248 **Statistical analysis**

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

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

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

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

275 and “0” for “no”) and 10) type of intervention (“1” for electrotherapy and “0” for
276 non-electrotherapy).

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

283 **DISCUSSION**

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

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

299 The results of this study are likely to influence authors, funding agencies,
300 ethics committees, journal editors and peer reviewers to improve the reporting and
301 review process for pilot and feasibility trials. We expect that our results will provide
302 important baseline data which can be used for comparative purposes in the
303 evaluation of strategies aimed to improve the reporting and quality of reports of
304 pilot and feasibility trials.

306 **Ethics and dissemination**

307 This survey does not require ethical approval because it is a methodological
308 review of published reports of randomised controlled trials. The results of this study
309 will be disseminated through peer review publication and presentation at
310 international conferences.

311

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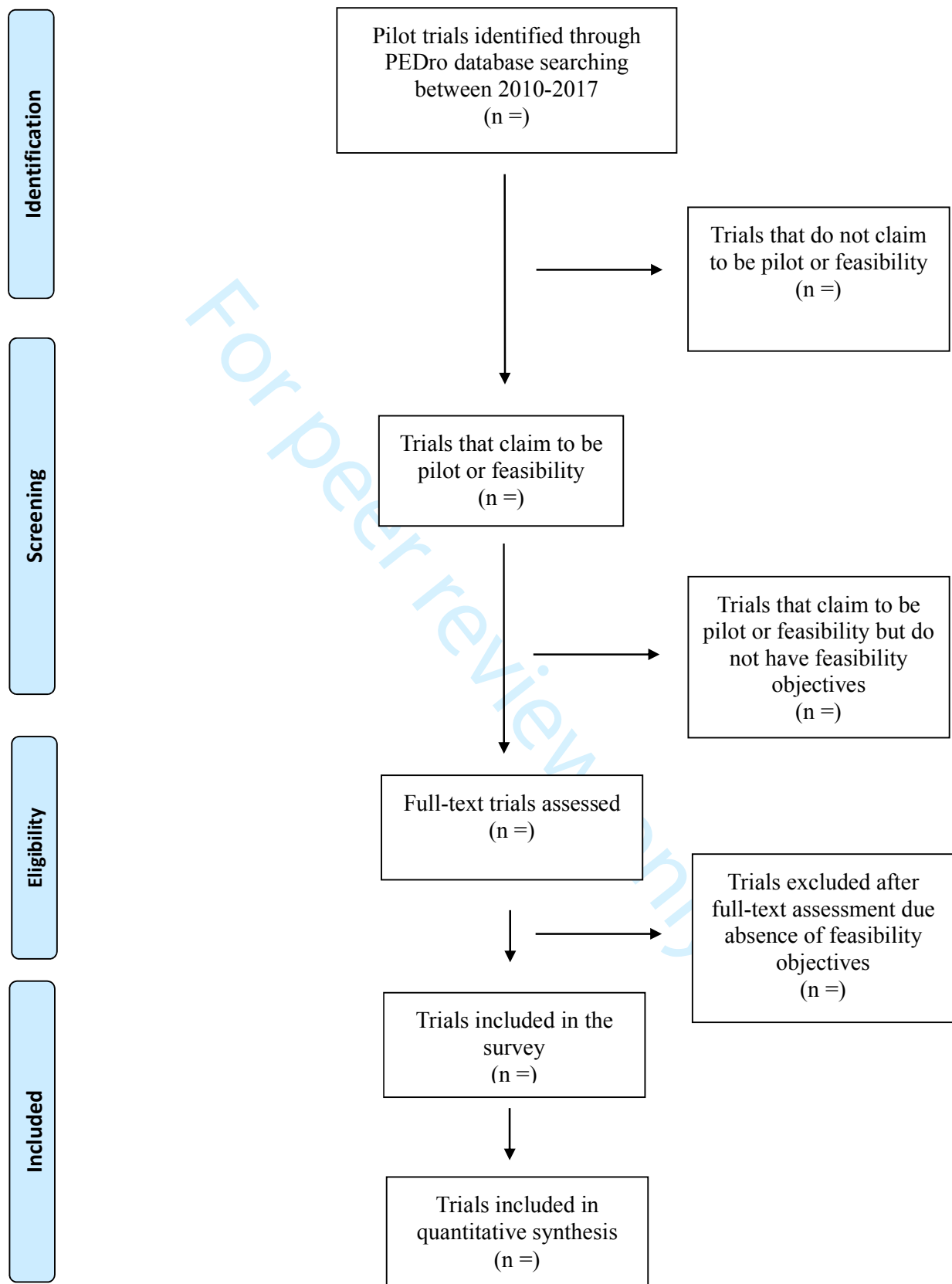
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Primary Subject Heading:	Research methods
Secondary Subject Heading:	Evidence based practice, Rehabilitation medicine
Keywords:	Pilot, Clinical trial, Dress rehearsal, Feasibility, Vanguard

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FEASIBILITY TRIALS FOR PHYSIOTHERAPY INTERVENTIONS: A
STUDY PROTOCOL**

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AUTHORS' CONTRIBUTIONS

LFCS wrote the first draft.

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

LT and AM conceptualized the study.

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

COMPETING INTEREST

The authors have no conflicts of interest to declare.

ABSTRACT

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

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

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

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

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

64 **Strengths and limitations of this study**

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

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

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

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

The number of randomised controlled trials in Physiotherapy has grown exponentially over time³⁰. Time and funding are resources that could be saved by conducting high-quality pilot and feasibility studies. To our knowledge, the reporting quality of pilot and feasibility trails of Physiotherapy interventions using the new extension of the CONSORT statement for randomised pilot and feasibility trials has not yet been performed, nor the factors associated with better reporting 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.

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.

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

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

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

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”.

174 **Studies selection**

Two independent reviewers will screen the title and abstracts of the trials in the search results to identify trials, which claim to be a pilot or feasibility trial. The title, abstract and, if necessary, full-text of these self-identified pilot or feasibility trials will be evaluated to identify the sub-set of articles which contain objective(s) linked with feasibility. Any disagreements between reviewers will be resolved by discussion or, if necessary, arbitration by a third reviewer. Figure 1 presents the flow diagram used to guide article selection.

Insert figure 1 here

Data extraction

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

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

209 The reviewers will independently extract the data using an electronic data
210 extraction form designed for this survey. The data extraction form will be created
211 using information from the CONSORT extension to randomised pilot and feasibility
212 trials. We will pilot the data extraction forms on ten randomly selected trials before
213 proceeding with full data extraction to ensure all reviewers extract data consistently
214 and to ensure the data extraction form is unambiguous and free from errors.
215 Discrepancies between the two reviewers will be resolved by discussion and by
216 consulting the published explanation of the CONSORT checklists. If necessary,
217 arbitration by a third reviewer will help to provide consensus on the data extracted.
218 In order to improve the clarity regarding inclusions and exclusions and to increase
219 accuracy and consistency among the reviewers, between reviewer agreements will
220 be measured using the Kappa coefficients using an initial trial run involving 10
221 articles per reviewer. If adequate reliability will be not achieved, additional training
222 or improvement in the data extraction form will be undertaken.

PEDro scale scores, subdiscipline of Physiotherapy, intervention, language of publication and year of publication will be downloaded from PEDro. The PEDro scale is an 11-item scale which methodological quality and completeness of statistical reporting of reports of randomised controlled trials.³⁵ The items are: 1) eligibility criteria and source of subjects; 2) random allocation; 3) concealed allocation; 4) baseline comparability; 5) blinding of subjects; 6) blinding of therapists; 7) blinding of assessors; 8) > 85% follow-up; 9) intention-to-treat analysis; 10) between-group statistical comparisons; and 11) reporting of point measures and measures of variability.³⁵ Each item is rated as “yes” (unambiguously achieved) or “no”, with the number of “yes” responses for items 2-11 tallied to give the total PEDro score (out of 10). Both the individual items (coded as “0” for “no” or “1” for “yes”) and the total PEDro score (range, 0 to 10) will be downloaded. There is evidence that PEDro scale has higher reliability for individual ratings and consensus ratings compared to the Cochrane risk of bias^{35, 38}. Also, PEDro scale is strongly correlated ($r=0.83$; 95% CI 0.76 to 0.88) with the Cochrane Risk of Bias scale³⁹. The subdiscipline of Physiotherapy codes are: cardiothoracic, continence and women’s health, ergonomics and occupational health, gerontology, musculoskeletal, neurology, oncology, orthopaedics, paediatrics and sports or no appropriate value. Each trial can be assigned up to three codes for subdiscipline, in our study we will select the most applicable subdiscipline and this will be coded as a dummy variable. The language of publication will be coded to produce two different variables: “1” for English and “0” for languages other than English, and Chinese as “0” and all other languages as “1”. The year of publication will be subtracted from 2017 to produce an “age” (in years) for each trial.

One reviewer will determine if the trial was registered and if the journal of publication for each trial endorses the CONSORT statement. Clinical trial registration will be extracted from the full article or, if not reported in the full article, by searching the International Clinical Trials Registry Platform (<http://apps.who.int/trialsearch/>) and will be coded as “1” for “yes” or “0” for “no”. Journal endorsement of the CONSORT statement will be achieved by reviewing the list of journals on the CONSORT web-site⁴⁰ and, if necessary, visiting journal websites and reviewing the instructions for authors and other editorial policies.

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

Patient and Public Involvement

Patients and or public were not involved on this study.

Statistical analysis

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

The primary analysis will be a descriptive analysis of completeness of

reporting of the abstracts and full articles of the pilot or feasibility trials. The frequency that each item is scored as “Reported”, “Inadequately reported”, “Not reported” and “Not applicable” for the CONSORT pilot and feasibility trials checklist and CONSORT pilot and feasibility trials abstracts checklist will be tabulated. The mean (standard deviation) summary score will be calculated for each checklist.

In the secondary analysis, we will perform a Poisson regression analysis to determine which study characteristics are associated with greater completeness reporting. Two independent models will be built, one using the summary score for the CONSORT pilot and feasibility trials checklist (i.e., for the full article) as the dependent variable and the second model using the summary score for the CONSORT pilot and feasibility trials abstracts checklist. Independent variables for both models will be: 1) publication in a journal which endorses CONSORT^{12, 13} (“1” for “yes” or “0” for “no”) 2) trial funded¹⁴ (“1” for “yes” or “0” for “no”) 3) sample size¹⁴ (as a continuous variable), 4) reported trial registration number (“1” for “yes” and “0” for “no”), 5) total PEDro score (continuous variable, 0-10), 6) most applicable subdiscipline of Physiotherapy²⁷ (coded as dummy variables), 7) language of publication (“1” for English and “0” for all other languages), 8) non-Chinese reports (“1” for “yes” and “0” for “trials published in languages other than Chinese”), 9) number of authors (continuous variable), 10) reporting allocation concealment (PEDro scale item 3, “1” for “yes” and “0” for “no”).

We will use Generalised Estimating Equation (GEE) analysis, assuming an exchangeable correlation structure, to explore factors associated with completeness of reporting. GEE allows us to model possible correlation or similarity of the papers published within the same journal. All analyses will be performed using SAS 9.2

297 (Cary, NC).

298

299 **DISCUSSION**

300 This study will be the first to describe the completeness of reporting of pilot
301 or feasibility trials from a representative sample on the field of Physiotherapy using
302 the CONSORT extension to randomised pilot and feasibility trials. This is important
303 as good reporting, or transparency, will provide sufficient information about the
304 methods and results of the trial to guide clinical practice and further research to both
305 clinicians and researchers.

306 The transparency in reporting randomised controlled trials has improved
307 since the introduction of the CONSORT statement.¹² A number of other factors are
308 also associated with better trial quality, including being funded¹⁴, prospectively
309 registered¹³, published in English¹⁵, and having larger sample sizes.^{14, 29} Whether
310 these variables are also associated with a better reporting quality of pilot or
311 feasibility studies has not been rigorously investigated. To the best of our
312 knowledge, only one study has evaluated quality of reporting of pilot studies⁷. That
313 study did not use a scale or checklist to evaluate reporting, nor did it test for
314 possible factors that could predict quality.⁷

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316 **Ethics and dissemination**

317 This survey does not require ethical approval because it is a methodological
318 review of published reports of randomised controlled trials. The results of this study
319 will be disseminated through peer review publication and presentation at
320 international conferences.

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457 **Figure 1:** Study flow diagram

458

For peer review only

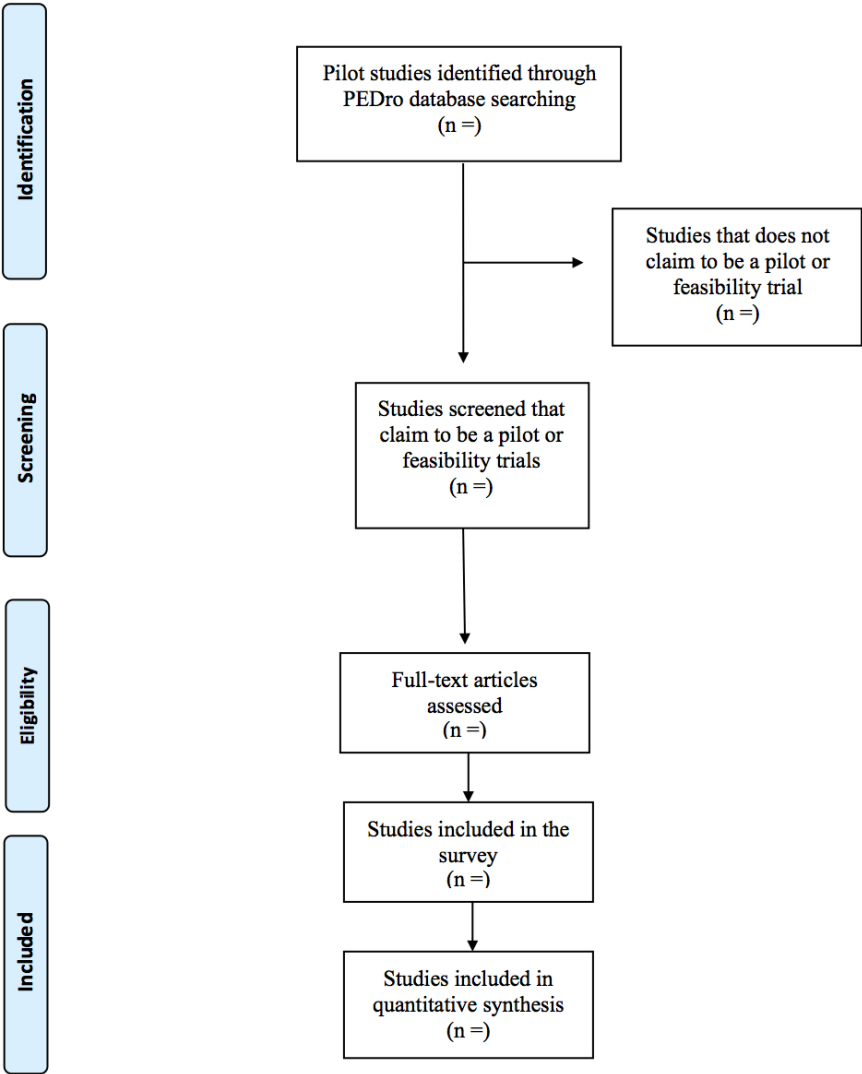


Figure 1: Study flow diagram

BMJ Open

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

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AUTHORS' CONTRIBUTIONS

LFCS wrote the first draft.

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

LT and AM conceptualized the study.

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

COMPETING INTEREST

The authors have no conflicts of interest to declare.

ABSTRACT

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

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

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

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

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

64 **Strengths and limitations of this study**

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

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

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

The number of randomised controlled trials in Physiotherapy has grown exponentially over time³⁰. Time and funding are resources that could be saved by conducting high-quality pilot and feasibility studies. To our knowledge, the reporting quality of pilot and feasibility trails of Physiotherapy interventions using the new extension of the CONSORT statement for randomised pilot and feasibility

124 trials has not yet been performed, nor the factors associated with better reporting
125 identified.

126 **OBJECTIVES**

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

138 **METHODS**

139 **Study design**

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

144 **Eligibility criteria**

145 We will include all reports of randomised controlled trials indexed in the
146 Physiotherapy Evidence Database (PEDro: www.pedro.org.au) that claim to be a
147 pilot or feasibility trial. We will only include trials published in 2011-2017 which
148 are fully indexed in PEDro (in-process trials, which have not had search terms and

149 PEDro scores allocated, will not be included). We decided to only include trials
150 published after 2010 because the International Committee of Medical Journal
151 Editors (ICMJE) stated that all trials started after July 2005 should be registered in a
152 free, publicly available and electronically searchable register^{31, 32} and also because
153 the last update of the CONSORT statement was published in 2010. There will be no
154 language restrictions.

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

169 **Search strategy**

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

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6 175 **Study selection**

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

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33 187 **Data extraction**

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35 188 Two independent reviewers will classify the reason(s) to conduct a pilot or
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37 189 feasibility for each included trial. There are several reasons for conducting pilot and
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39 190 feasibility studies. These reasons could be grouped under some broad
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41 191 classifications³⁷. A widely known tutorial⁴ aimed to provide a detailed examination
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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
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47 194 place as part of the main study), 2) resources (time and budget), 3) management
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49 195 (human and data optimization) or 4) scientific (issues like treatment safety).⁴ If
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51 196 more than one category is identified for an included trial, we will code for all
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55 197 relevant categories and indicate which category is linked to the primary objective of
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198 the trial. The number of subjects randomised and whether the pilot or feasibility
199 trial recommends that a large-scale trial will be conducted will also be recorded.

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

210 The reviewers will independently extract the data using an electronic data
211 extraction form designed for this survey. The data extraction form will be created
212 using information from the CONSORT extension to randomised pilot and feasibility
213 trials. We will pilot the data extraction forms on ten randomly selected trials before
214 proceeding with full data extraction to ensure all reviewers extract data consistently
215 and to ensure the data extraction form is unambiguous and free from errors.
216 Discrepancies between the two reviewers will be resolved by discussion and by
217 consulting the published explanation of the CONSORT checklists. If necessary,
218 arbitration by a third reviewer will help to provide consensus on the data extracted.
219 In order to improve the clarity regarding inclusions and exclusions and to increase
220 accuracy and consistency among the reviewers, between reviewer agreements will
221 be measured using the Kappa coefficients using an initial trial run involving 10

articles per reviewer. If adequate reliability will be not achieved, additional training or improvement in the data extraction form will be undertaken.

PEDro scale scores, subdiscipline of Physiotherapy, intervention, language of publication and year of publication will be downloaded from PEDro. The PEDro scale is an 11-item scale which methodological quality and completeness of statistical reporting of reports of randomised controlled trials.³⁵ The items are: 1) eligibility criteria and source of subjects, 2) random allocation, 3) concealed allocation, 4) baseline comparability, 5) blinding of subjects, 6) blinding of therapists, 7) blinding of assessors, 8) > 85% follow-up, 9) intention-to-treat analysis, 10) between-group statistical comparisons, and 11) reporting of point measures and measures of variability.³⁵ Each item is rated as “yes” (unambiguously achieved) or “no”, with the number of “yes” responses for items 2-11 tallied to give the total PEDro score (out of 10). Both the individual items (coded as “0” for “no” or “1” for “yes”) and the total PEDro score (range, 0 to 10) will be downloaded. There is evidence that PEDro scale has higher reliability for individual ratings and consensus ratings compared to the Cochrane risk of bias^{35, 38}. Also, PEDro scale is strongly correlated ($r=0.83$, 95% CI 0.76 to 0.88) with the Cochrane Risk of Bias scale³⁹. On the other hand, a meta-epidemiological study found discrepancies in terms of clinical trial’s quality using PEDro and Cochrane Risk of Bias scale⁴⁰. The subdiscipline of Physiotherapy codes are: cardiothoracic, continence and women’s health, ergonomics and occupational health, gerontology, musculoskeletal, neurology, oncology, orthopaedics, paediatrics and sports or no appropriate value. Each trial can be assigned up to three codes for subdiscipline, in our study we will select the most applicable subdiscipline and this will be coded as a dummy variable. The language of publication will be coded to produce two different variables: “1”

247 for English and “0” for languages other than English, and Chinese as “0” and all
248 other languages as “1”. The year of publication will be subtracted from 2017 to
249 produce an “age” (in years) for each trial.

250 One reviewer will determine if the trial was registered and if the journal of
251 publication for each trial endorses the CONSORT statement. Clinical trial
252 registration will be extracted from the full article or, if not reported in the full article,
253 by searching the International Clinical Trials Registry Platform
254 (<http://apps.who.int/trialsearch/>) and will be coded as “1” for “yes” or “0” for “no”.
255 Journal endorsement of the CONSORT statement will be achieved by reviewing the
256 list of journals on the CONSORT web-site⁴¹ and, if necessary, visiting journal web-
257 sites and reviewing the instructions for authors and other editorial policies.

258 One reviewer will collect the journal impact factor if available at the time of
259 pilot trial publication (as a continuous variable) through a search at Journal Citation
260 Reports website (<https://jcr.incites.thomsonreuters.com>). Other variables, including
261 number of authors (as a continuous variable), source of funding, declaration of
262 conflict of interests and sample size (as a continuous variable), will be collected by
263 one reviewer through the electronic data extraction form designed for this review.

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265 **Patient and Public Involvement**

266 Patients and or public were not involved on this study.

267

268 **Statistical analysis**

269 Firstly, we will calculate the number, percentage and 95% confidence
270 interval of trials indexed in PEDro that claim to be a feasibility or pilot trial that
271 evaluate feasibility. The PEDro confidence interval calculator will be used to

272 calculate the 95% confidence interval.⁴² We will also compute the aspect of
273 feasibility evaluated in the primary objective(s) of the pilot or feasibility trials.

274 The primary analysis will be a descriptive analysis of completeness of
275 reporting of the abstracts and full articles of the pilot or feasibility trials. The
276 frequency that each item is scored as “Reported”, “Inadequately reported”, “Not
277 reported” and “Not applicable” for the CONSORT pilot and feasibility trials
278 checklist and CONSORT pilot and feasibility trials abstracts checklist will be
279 tabulated. The mean (standard deviation) summary score will be calculated for each
280 checklist.

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

296 We will use Generalised Estimating Equation (GEE) analysis, assuming an

exchangeable correlation structure, to explore factors associated with completeness of reporting. GEE allows us to model possible correlation or similarity of the papers published within the same journal. All analyses will be performed using SAS 9.2 (Cary, NC).

301

302 **DISCUSSION**

303 This study will be the first to describe the completeness of reporting of pilot or feasibility trials from a representative sample on the field of Physiotherapy using the CONSORT extension to randomised pilot and feasibility trials. This is important as good reporting, or transparency, will provide sufficient information about the methods and results of the trial to guide clinical practice and further research to both clinicians and researchers.

309 The transparency in reporting randomised controlled trials has improved since the introduction of the CONSORT statement.¹² A number of other factors are also associated with better trial quality, including being funded¹⁴, prospectively registered¹³, published in English¹⁵, and having larger sample sizes.^{14, 29} Whether these variables are also associated with a better reporting quality of pilot or feasibility studies has not been rigorously investigated. To the best of our knowledge, only one study has evaluated quality of reporting of pilot studies⁷. That study did not use a scale or checklist to evaluate reporting, nor did it test for possible factors that could predict quality.⁷

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319 **Ethics and dissemination**

320 This survey does not require ethical approval because it is a methodological review of published reports of randomised controlled trials. The results of this study

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5 323 international conferences.
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Figure 1: Study flow diagram

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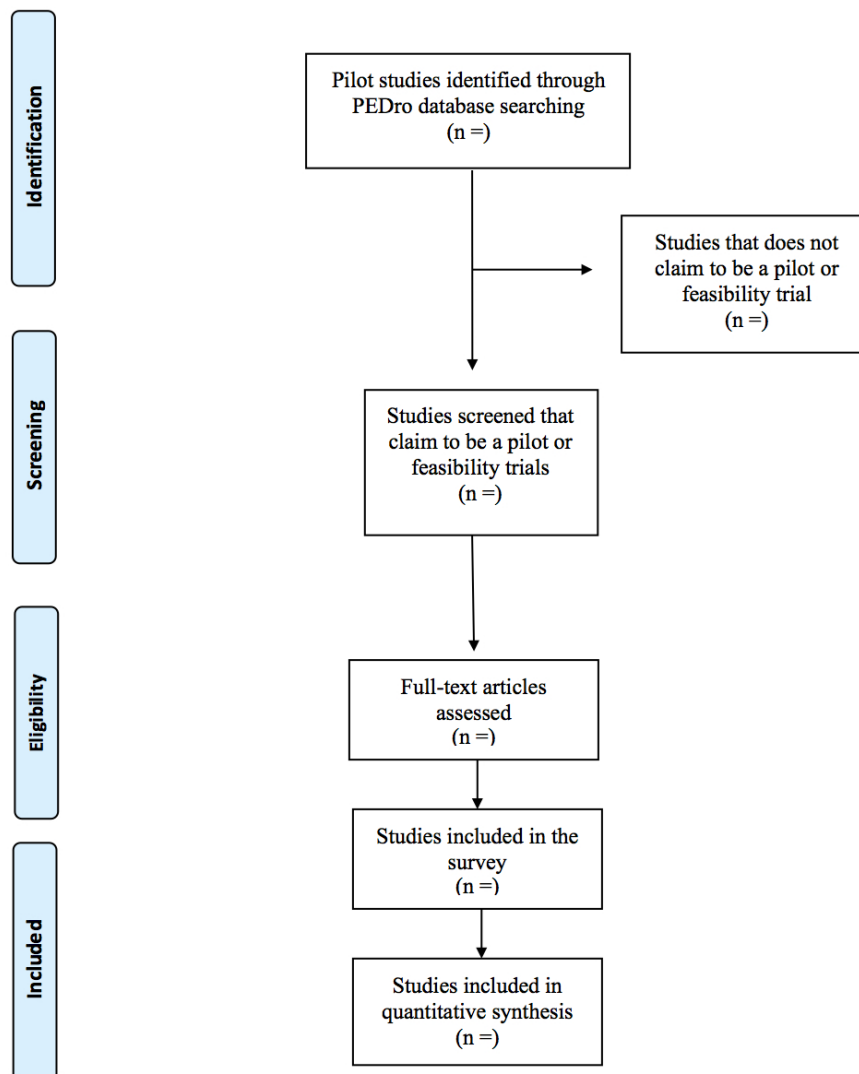


Figure 1: Study flow diagram