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

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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, 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.

INTRODUCTION

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

Evaluations of published pilot and feasibility trials suggests that the trials may not actually be evaluating feasibility[6,7] and are being poorly reported.[7] In a small sample of 93 pilot and feasibility trials published in Indian biomedical journals, 68% of trials performed between-group statistical comparisons and none reported feasibility objectives[7]. In addition, an ad-hoc list of trial characteristics was used to evaluate reporting, rather than a scale or checklist. Another survey of 191 pilot and feasibility trials published in 1987-2015 in a single journal (i.e. *Clinical 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 trials[10-15] and the abstracts of trials[16-18] 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.

OBJECTIVES

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

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

METHODS

Study design

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

Eligibility criteria

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

We selected the PEDro database as the source of trial reports because it is one of the most comprehensive indexes of reports of randomised controlled trials evaluating physiotherapy interventions[32, 33] plus nearly all trials indexed are rated for methodological quality and the completeness of statistical reporting using the PEDro scale[34] and are coded for the area (or subdiscipline) of physiotherapy practice and type of intervention. To be eligible for inclusion on PEDro, trials must involve comparison of at least two interventions (or an intervention and control condition) applied to subjects who are representative of those who the interventions might be applied to in the course of clinical practice, with at least one of the interventions under evaluation being part of physiotherapy practice. In addition, all trials included in PEDro must involve random (or intend-to-be-random) allocation of subjects into interventions, and be fully published in a peer-reviewed journal.[35]

Search strategy

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

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 pilot or feasibility objective(s) for each included trial. The four categories will be: 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.

The two independent reviewers will also complete the CONSORT pilot and feasibility trials checklist (40 items) and the CONSORT pilot and feasibility trials abstracts checklist (16 items; note, the "author" item was omitted as this relates to conference abstracts only) for each trial.[8, 9] The CONSORT checklists include items related to the title, trial design, methods, results, conclusions, registration and funding. Each item will be rated as "Reported", "Inadequately reported", "Not reported" or "Not Applicable". Summary scores for the CONSORT pilot and feasibility trials checklist (range, 0 to 40) and CONSORT pilot and feasibility trials abstracts checklist (range, 0 to 16) will be calculated by tallying the items scored as "Reported".

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

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.[34] 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.[34] 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. 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. 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-site[36] 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.

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.[37] 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 funded[14] ("1" for "yes" or "0" for "no") 3) sample size[14] (as a continuous variable); 4) reported trial registration number ("1" for "yes" and "0" for "no"), 5) total PEDro score (continuous variable, 0-10); 5) most applicable subdiscipline of physiotherapy[27] (coded as dummy variables), 6) language of publication ("1" for English and "0" for all other languages), 7) non-Chinese reports ("1" for "yes" and "0" for "no"), 8) number of authors (continuous variable), 9) reporting allocation concealment (PEDro scale item 3; "1" for "yes"

and "0" for "no") and 10) type of intervention ("1" for electrotherapy and "0" for non-electrotherapy).

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).

DISCUSSION

This study will be the first to describe the completeness of reporting of pilot or feasibility trials for an entire field of healthcare (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.

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 funded[14], prospectively registered[13], published in English[15], 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 studies[7]. That study did not use a scale or checklist to evaluate reporting, nor did it test for possible factors that could predict quality.[7]

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

Ethics and dissemination

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 will be disseminated through peer review publication and presentation at international conferences.

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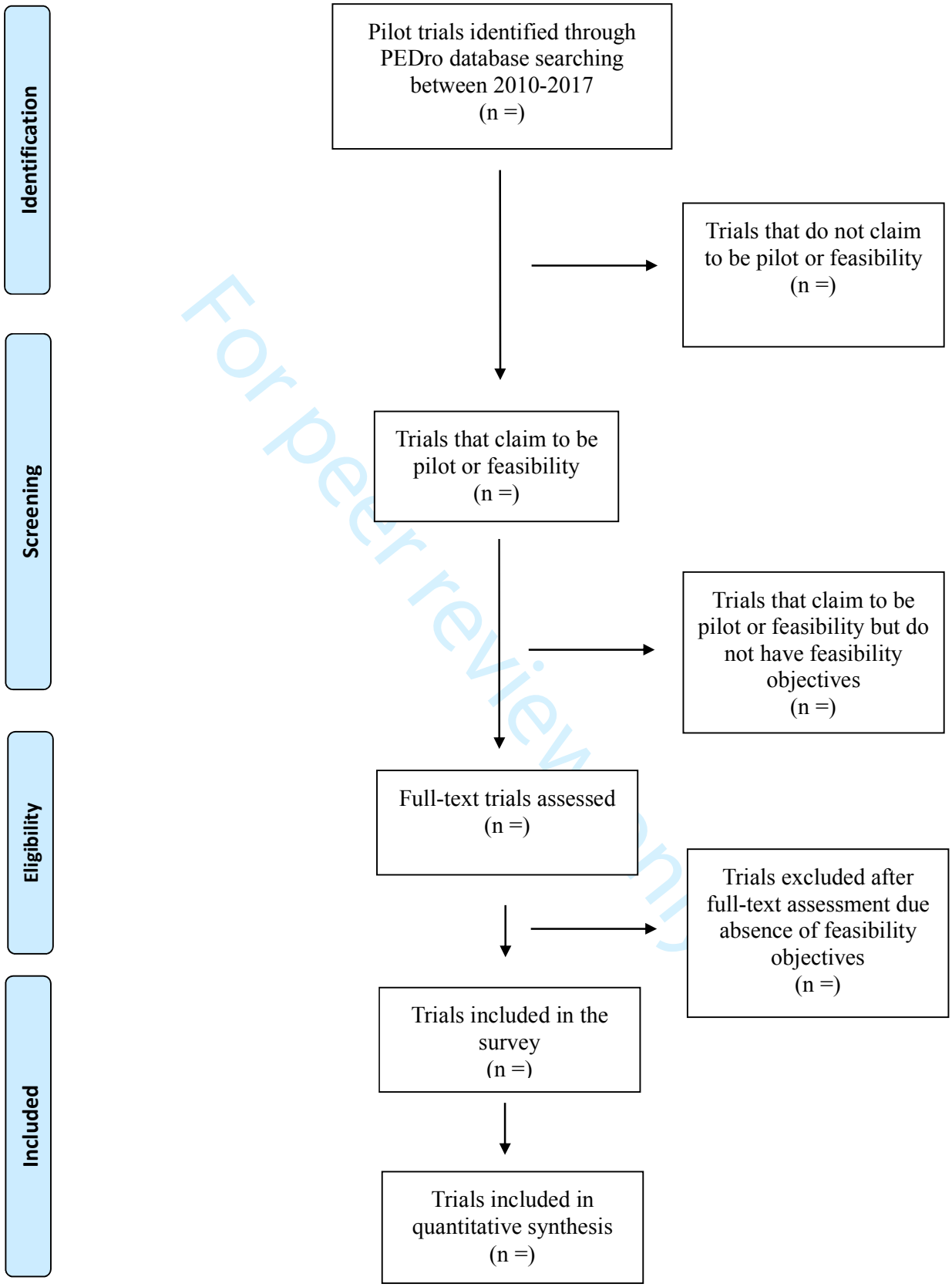

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AUTHORS' CONTRIBUTIONS

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

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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

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

INTRODUCTION

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

Evaluations of published pilot and feasibility trials suggests that the trials may not actually be evaluating feasibility[6,7] and are being poorly reported.[7] In a small sample of 93 pilot and feasibility trials published in Indian biomedical journals, 68% of trials performed between-group statistical comparisons and none reported feasibility objectives[7]. In addition, an ad-hoc list of trial characteristics was used to evaluate reporting, rather than a scale or checklist. Another survey of 191 pilot and feasibility trials published in 1987-2015 in a single journal (i.e. *Clinical 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 trials[10-15] and the abstracts of trials[16-18] 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 time[30]. 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.

OBJECTIVES

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

METHODS

Study design

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

Eligibility criteria

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

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

We selected PEDro database as the source of trial reports because PEDro is one of the most comprehensive indexes of reports of randomised controlled trials evaluating Physiotherapy interventions[33, 34]. Moreover, all trials indexed on PEDro are rated for methodological quality and the completeness of statistical reporting using the PEDro scale[35] and are coded for the area (or subdiscipline) of Physiotherapy practice and type of intervention. To be eligible for inclusion on PEDro, trials must involve comparison of at least two interventions (or an intervention and control condition) applied to subjects who are representative of those who the interventions might be applied to in the course of clinical practice, with at least one of the interventions under evaluation being part of Physiotherapy practice. In addition, all trials included in PEDro must involve random (or intend-to-be-random) allocation of subjects into interventions, and be fully published in a peer-reviewed journal.[36]

Search strategy

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

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 classifications[37]. A widely known tutorial[4] 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.

The two independent reviewers will also complete the CONSORT pilot and feasibility trials checklist (40 items) and the CONSORT pilot and feasibility trials abstracts checklist (16 items; note, the "author" item was omitted as this relates to conference abstracts only) for each trial.[8, 9] The CONSORT checklist include items related to the title, trial design, methods, results, conclusions, registration and funding. Each item will be rated as "Reported", "Inadequately reported", "Not reported" or "Not Applicable". Summary scores for the CONSORT pilot and feasibility trials checklist (range, 0 to 40) and CONSORT pilot and feasibility trials abstracts checklist (range, 0 to 16) will be calculated by tallying the items scored as "Reported".

The reviewers will independently extract the data using an electronic data extraction form designed for this survey. The data extraction form will be created using information from the CONSORT extension to randomised pilot and feasibility trials. We will pilot the data extraction forms on ten randomly selected trials before proceeding with full data extraction to ensure all reviewers extract data consistently and to ensure the data extraction form is unambiguous and free from errors. Discrepancies between the two reviewers will be resolved by discussion and by consulting the published explanation of the CONSORT checklists. If necessary, arbitration by a third reviewer will help to provide consensus on the data extracted. In order to improve the clarity regarding inclusions and exclusions and to increase accuracy and consistency among the reviewers, between reviewer agreements will 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 scale[39]. 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-site[40] 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), 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 funded[14] ("1" for "yes" or "0" for "no") 3) sample size[14] (as a continuous variable), 4) reported trial registration number ("1" for "yes" and "0" for "no"), 5) total PEDro score (continuous variable, 0-10), 5) most applicable subdiscipline of Physiotherapy[27] (coded as dummy variables), 6) language of publication ("1" for English and "0" for all other languages), 7) non-Chinese reports ("1" for "yes" and "0" for "trials published in languages other than Chinese"), 8) number of authors (continuous variable), 9) 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

(Cary, NC).

DISCUSSION

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.

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 funded[14], prospectively registered[13], published in English[15], 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 studies[7]. That study did not use a scale or checklist to evaluate reporting, nor did it test for possible factors that could predict quality.[7]

Ethics and dissemination

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 will be disseminated through peer review publication and presentation at international conferences.

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Figure 1: Study flow diagram

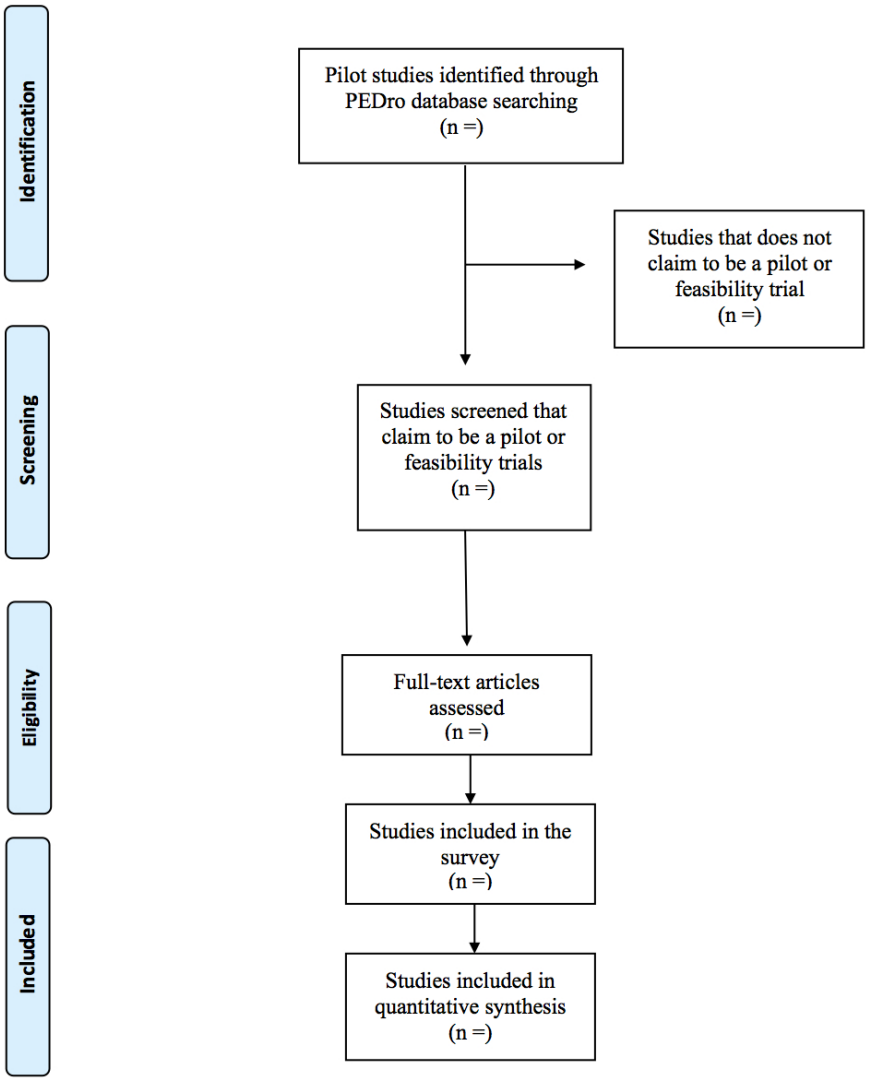

Figure 1: Study flow diagram

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

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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

and published in 2011-2017 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

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

INTRODUCTION

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

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The completeness of reporting of full published reports of randomised controlled trials[10-15] and the abstracts of trials[16-18] 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]

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

OBJECTIVES

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

METHODS

Study design

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

Eligibility criteria

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

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

We selected PEDro database as the source of trial reports because PEDro is one of the most comprehensive indexes of reports of randomised controlled trials evaluating Physiotherapy interventions[33, 34]. Moreover, all trials indexed on PEDro are rated for methodological quality and the completeness of statistical reporting using the PEDro scale[35] and are coded for the area (or subdiscipline) of Physiotherapy practice and type of intervention. To be eligible for inclusion on PEDro, trials must involve comparison of at least two interventions (or an intervention and control condition) applied to subjects who are representative of those who the interventions might be applied to in the course of clinical practice, with at least one of the interventions under evaluation being part of Physiotherapy practice. In addition, all trials included in PEDro must involve random (or intend-to-be-random) allocation of subjects into interventions, and be fully published in a peer-reviewed journal.[36]

Search strategy

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

Study selection

Two independent reviewers will screen titles and abstracts to identify references that 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 classifications[37]. A widely known tutorial[4] 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.

The two independent reviewers will also complete the CONSORT pilot and feasibility trials checklist (40 items) and the CONSORT pilot and feasibility trials abstracts checklist (16 items) (note, the "author" item was omitted as this relates to conference abstracts only) for each trial.[8, 9] The CONSORT checklist include items related to the title, trial design, methods, results, conclusions, registration and funding. Each item will be rated as "Reported", "Inadequately reported", "Not reported" or "Not Applicable". Summary scores for the CONSORT pilot and feasibility trials checklist (range, 0 to 40) and CONSORT pilot and feasibility trials abstracts checklist (range, 0 to 16) will be calculated by tallying the items scored as "Reported".

The reviewers will independently extract the data using an electronic data extraction form designed for this survey. The data extraction form will be created using information from the CONSORT extension to randomised pilot and feasibility trials. We will pilot the data extraction forms on ten randomly selected trials before proceeding with full data extraction to ensure all reviewers extract data consistently and to ensure the data extraction form is unambiguous and free from errors. Discrepancies between the two reviewers will be resolved by discussion and by consulting the published explanation of the CONSORT checklists. If necessary, arbitration by a third reviewer will help to provide consensus on the data extracted. In order to improve the clarity regarding inclusions and exclusions and to increase accuracy and consistency among the reviewers, between reviewer agreements will 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 scale[39]. On the other hand, a meta-epidemiological study found discrepancies in terms of clinical trial's quality using PEDro and Cochrane Risk of Bias scale[40]. 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-site[41] 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 if available 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.[42] 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 funded[14] ("1" for "yes" or "0" for "no") 3) sample size[14] (as a continuous variable), 4) reported trial registration number ("1" for "yes" and "0" for "no"), 5) total PEDro score (continuous variable, 0-10), 5) most applicable subdiscipline of Physiotherapy[27] (coded as dummy variables), 6) language of publication ("1" for English and "0" for all other languages), 7) non-Chinese reports ("1" for "yes" and "0" for "trials published in languages other than Chinese"), 8) number of authors (continuous variable), 9) 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 (Cary, NC).

DISCUSSION

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.

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 funded[14], prospectively registered[13], published in English[15], 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 studies[7]. That study did not use a scale or checklist to evaluate reporting, nor did it test for possible factors that could predict quality.[7]

Ethics and dissemination

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

will be disseminated through peer review publication and presentation at international conferences.

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460 **Figure 1:** Study flow diagram

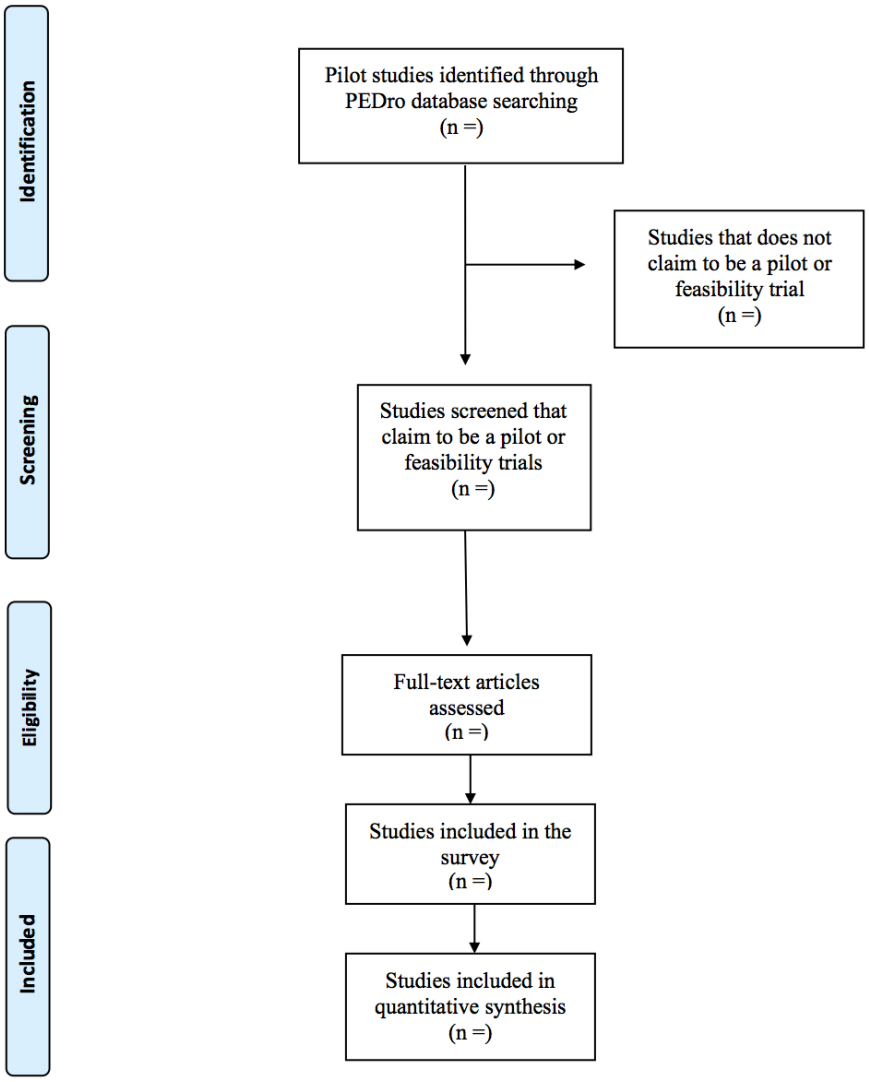

Figure 1: Study flow diagram