Evaluating self-help and education descriptors as a physiotherapy rehabilitation intervention in knee osteoarthritis and its impact on clinical practice.

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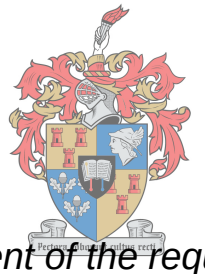

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DECLARATION

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ABSTRACT

Background

The regular use of clinical practice guidelines (CPGs) has been promoted as a way of improving care, standardising clinical decisions and treatment. However, the intervention's reported in the randomised controlled clinical trials (RCTs) used in CPGs is typically not fully described and may lack description making it difficult to replicate in clinical practice. There was thus need to investigate ways in which the CPG-recommended interventions could be delineated into a more clinician-friendly format, so that it could be easier to replicate in practice and therefore ensure evidence-based practice. This study will form part of a larger project.

Objective

To evaluate the descriptions of physiotherapy rehabilitation interventions of self-help and education for people with specifically knee osteoarthritis (OA) in CPGs and more recent RCTs, in terms of the detail provided, and how readily they could be replicated in clinical practice. It will act as a process to ascertain logistics of methods required to extract data for intervention descriptions and form part of a larger project investigating methods in which CPGs can be made more clinician friendly.

Methodology

The most recent and the highest quality CPGs for community based rehabilitation for adults living with knee OA was accessed through data clearing houses. The CPGs were critically appraised using the iCACHE tool to ensure that the guideline is of the highest quality. The RCTs that were used to compile the systematic reviews on self-help and education in the CPGs for knee OA, was retrieved and evaluated. An updated search was conducted in Pubmed and PEDro computerised databases for the RCTs published after the CPGs release date. The quality of the RCTs was critically appraised by making use of the PEDro scale. A standard evaluation approach was then taken, using a recently-published checklist, the Template for Intervention Description and Replication Checklist (TIDieR) tool, to assess elements

of rehabilitation interventions used. Results were summarised using pie charts, tables or in narrative form.

Results

Two CPGs were retrieved and a total of nine RCTs trials included in this review. The results of the TIDieR revealed that certain aspects were adequately described, such as *'name of the intervention'* (77.78%), *'intervention rationale for essential elements'* (100%), *'description of the intervention procedures'* (88.89%), *'mode of delivery of intervention'* (100%) and *'details about the number; duration, intensity, and dose of intervention sessions'* (88.89%). Other aspects however scored less adequately such as *'intervention materials and details about how to access them'* (22.22%), *'details of intervention providers'* (44.44%), *'location of intervention delivery and key infrastructure'* (0%), *'details of any intervention tailoring'* (11.11%), *'any intervention modifications throughout the study'* (0%), and *'details of intervention fidelity assessment, monitoring, and level achieved'* (11.11%).

Conclusion

Despite the availability of evidence for the use of the self-help and education for knee OA in CPGs, there remains a lack of descriptions of the interventions within RCTs. Since the reproducibility of an intervention in a clinical setting forms a crucial part of adding value to research, the lack of description and difficulty in reproducing the interventions in clinical practice, is concerning. CPGs therefore fail to bridge the gap between best practice, patient choices and local context and strategies to address this gap need to be developed.

Key words: *self-help; education; rehabilitation; knee osteoarthritis (OA); clinical practice guidelines; randomised controlled clinical trials; TIDieR*

OPSOMMING

Agtergrond

Die gereelde gebruik van kliniese praktyk riglyne word aanbeveel as ‘n manier om versorging, kliniese besluite te standaardiseerd en behandeling te verbeter. Maar die behandelings metodes wat gerapporteer word in willekeurige gekontroleerde kliniese proefnemings wat gebruik word in kliniese praktyk riglyne, word tipies onvolledig beskryf wat dit uitdagend maak om weer te herhaal in kliniese praktyk. Daar is dus ‘n behoefte om maniere te ondersoek waardeur die kliniese praktyk riglyne aanbeveling en behandelinge kan afbreek na ‘n meer klinikus vriendelike formaat, sodat dit makliker sal wees om dit te herhaal in die praktyk en verseker dus so ‘n bewys gebaseerde praktyk. Die studie vorm deel van ‘n groter projek en skakel as deel van dit in.

Doel

Om die beskrywing van fisioterapie rehabilitasie behandelings van self-help en onderrig van pasiënte, met spesifiek knie osteartritis, in kliniese praktyk riglyne en meer onlangse willekeurige gekontroleerde kliniese proefnemings (in terme van behandelings besonderhede wat beskikbaar is) te evalueer asook hoe gemaklik dit herhaal word in kliniese praktyk. Dit sal as ‘n voorloper dien om die metode op te stel vir die groter projek wat ondersoek instel om kliniese praktyk riglyne meer klinikus vriendelik te maak.

Metodiek

Data stelsels is gebruik om die nuutste en beste kwaliteit kliniese praktyk riglyne vir die gemeenskap gebaseerde rehabilitasie van volwassenes met knie osteoartritis te verkry. Die kliniese praktyk riglyne is krities getakseer deur gebruik te maak van die iCACH instrument om te verseker dat die riglyne van die hoogste gehalte is. Die willekeurige gekontroleerde kliniese proefnemings wat gebruik is om die sistemiese

oorsig oor self-help en onderrig in die kliniese praktyk riglyne vir knie osteoartritis, saam te stel, is nagevors en ge-evalueer. ‘n Opgedateerde ondersoek is gedoen in Pubmed en PEDro se gerekenariseerde databasisse vir die willekeurige gekontroleerde kliniese proefnemings wat ná kliniese praktyk riglyne se vrystellingsdatum gepubliseer is. Die PEDro skaal is gebruik om die kwaliteit van die willekeurige gekontroleerde kliniese proefnemings krities te takseer. ‘n Standaard evaluerings aanslag is toe gevolg deur gebruik te maak van die nuutste gepubliseerde kontrolelys, Die Templaat vir Intervensie beskrywing en replikasie kontrolelys (TIDieR) om elemente van die rehabilitasie intervensie te assesseer. Sirkel grafieke, tabelle of beskrywings is gebruik om die resultate op te som.

Resultate

Twee kliniese praktyk riglyne is opgespoor en nege willekeurige gekontroleerde kliniese proefnemings is ingesluit in die oorsig. Die resultate van die TIDieR toon dat sekere aspekte voldoende beskryf was soos byvoorbeeld naam van die intervensie (77,78%), intervensie rationaal vir noodsaaklike elemente (100%), beskrywing van die intervensie prosedure (88,89%), wyse van die intervensie (100%) en detail van die getal, duur, intensiteit en dosis van die intervensiesessies (88,89%). Ander aspekte was minder doeltreffend soos byvoorbeeld intervensie apparaat en inligting, hoe om dit te bekom (22,22%), inligting oor intervensie verskaffers (44,44%), plek waar intervensie plaasvind, die infrastruktuur (0%), inligting oor enige intervensie spesialisering (11,11%) enige intervensie verbetering in die studie (0%), en inligting oor die intervensie assessering, monetering en die vlak van sukses behaal.

Samevatting

Ten spyte van die beskikbaarheid van bewyse vir die gebruik van self-help en onderrig van knie osteoartritis in kliniese praktyk riglyne , bestaan daar ‘n leemte vir die voorskrifte van die behandelings metodes in willekeurige gekontroleerde kliniese proefnemings. Aangesien die reproduseerbaarheid van ‘n behandelings metode in

‘n kliniese omgewing ‘n deurslaggewende rol in die navorsing speel, is die gebrek aan beskrywing en die probleem van reproduksie van die behandelings metodes in die kliniese praktyk, ‘n bekommernis.

Daarom faal kliniese praktyk riglyne om die gaping te oorbrug wat ontstaan tussen die beste behandeling, die pasient se keuse, plaaslike konteks en om strategieë aan te spreek. Hierdie gaping moet dus oorbrug en ontwikkel word.

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GLOSSARY

Acronyms and Abbreviations

AIDS	Acquired Immunodeficiency Syndrome
CPGs	Clinical Practice Guidelines
HIV	Human Immunodeficiency Virus
iCAHE	International Centre for Allied Health Evidence
ICF	International Classification of Function framework
NGCH	National Guideline Clearing House
NHMRC	National Health and Medical research Council
NICE	National Institute for Health and Excellence
NZGG	New Zealand Guidelines Group
OA	Osteoarthritis
OARSI	Osteoarthritis Research Society International
PHC	Primary Health Care
RCTs	Randomised Controlled Clinical Trials
SA	South Africa
SIGN	Scottish International Guideline Network
SRs	Systematic Reviews
TB	Tuberculosis
TIDieR	Template for Intervention Description and Replication
WHO	World Health Organization

Definitions

Rehabilitation

It is the process that aims to enable people living with disabilities to reach and restore their highest level of function (World Health Organization, 2017).

Primary Health Hare

The basic healthcare that is universally accessible to everyone in the community through and at an affordable price (Kautzkyi & Tollmani, 2008).

Clinical practice guidelines

Statements that include recommendations that intend to optimize patient care. It is the result of a systematic review and an assessment of both the benefits and harms of alternative treatment options (Graham, Mancher, Wolman, Greenfield & Steinberg, 2011).

Self-help

A term used for aspects of care which a person can do for themselves with advice from the primary care team, such as the general practitioner, nurse, physiotherapist, occupational therapist and from information leaflets (National Clinical Guideline Centre, 2014).

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CHAPTER 1

INTRODUCTION

People living with disabilities are typically affected on a physical, psychological and social level (Lorenzo, Van Pletzen & Booyens, 2015). Considering that physical disability affects not only the individual, the family, the community, but also the economy of a country as since people living with disabilities frequently seek more health care (World Health Organization, 2016). Rehabilitation assists people living with disabilities to be more independent, maintain their dignity, maintain or regain their functional abilities and enhance their quality of life (World Health Organisation, 2017). Rehabilitation should therefore form part of any primary health care (PHC) setting and be accessible to all, and the World Health Organisation (WHO) Rehabilitation 2030 initiative aims to achieve just that (World Health Organisation, 2017). It is envisaged, that through ensuring that rehabilitation is offered at PHC settings, the burden of disabilities in the communities has the greatest chance of being addressed successfully and potentially be decreased (Van Geertruyden, Alberts, Modjadji, Meuleman, Fraeyman & Bastiaens, 2015).

However, since a large proportion of the South African population is affected by poverty and most parts are rural (Statistics South Africa, 2015), it is often challenging for people living with disabilities to access essential health and rehabilitation services at PHC level (Bongani & Benatar, 2014; Kautzkyi & Tollmani, 2008). Unfortunately people living with disabilities experience various barriers in accessing rehabilitation (Lorenzo et al., 2015) and the need has therefore arisen, based on the WHO Rehabilitation 2030 call, to ensure that every South African, living in any area, has access to the best possible form of rehabilitation at PHC level. It is therefore essential, especially in areas where resources are scarce, that ways are found to make rehabilitation more accessible to all (Kautzkyi & Tollmani, 2008), irrespective of where they live.

The regular use of clinical practice guidelines (CPGs) has been promoted as a way of improving care, and standardising clinical decisions and treatment (Kredo, Bernhardsson, Machingaidze, Young, Louw, Ochodo, Grimmer, 2016) within both urban and rural clinical settings. However, when looking at randomised controlled clinical trials (RCTs) which provide the baseline evidence for most CPGs that deal with intervention, it was also found that the description of the intervention often lacked detail and were inefficient for direct implementation and replication in clinical practice (Douet, Milne, Anstee, Habens, Young & Wright, 2013). Since the reproducibility of an intervention in a clinical setting forms a crucial part of adding value to research and ensuring evidence-based practice (Duet et al., 2013), there is a need to investigate ways in which the CPG recommended interventions could be delineated into a more clinician-friendly format. One way that has been proposed is to develop a flipchart or mobile application which would be easy to comprehend and implemented by any clinician in any setting, especially at PHC level. The development of such an application forms part of a larger funded project (Integrated, comprehensive evidence based rehabilitation guidelines for the South African Primary Health care context, project ethics number N16/03/036, Morris 2016-2019, ongoing project). A number of steps were however required before such an application could be developed, and subsequent studies would have to be conducted prior to conducting the main study.

However, since the methods to inform the larger project had yet to be developed, the following study aimed to ascertain the logistics and methodology required. It was hoped that the methods and logistics would be applied to other studies which would inform the larger project. As a starting point the main aim of this study was to investigate the detail of descriptions of physiotherapy rehabilitation interventions, specifically self-help and education as management, of adults with specifically knee osteoarthritis as reported in CPGs. The following thesis outlines the processes followed to achieve this study's aim and recommends what steps need to be taken to inform the larger funded project.

CHAPTER 2

LITERATURE REVIEW

2.1 Introduction

The following chapter presents a literature review of the current evidence and information which underpins the rationale for conducting this study. In this chapter an overview of key aspects which are important for this study is discussed.

2.2 The global burden of disability

Over the past decade, technological advances in the field of medicine have led to less people dying and more people ending up with a disability (Mayosi, Flisher, Lalloo, Sitas, Tollman & Bradshaw, 2009). People, who would have previously died due to an illness, are saved and find themselves living with disabilities which have a significant influence on their quality of lives (Howse, 2006). The person living with the disability, often cannot return to their previous level of function and work, which increases the financial burden on their family, society and the economy (Van den Broeck, 2016; Eide & Ingstad, 2013; Mayosi et al., 2009).

One of the main ways in which people sustain a disability is as a result of a chronic disease (Hung, Roos, Boockvar & Siu, 2012). A chronic disease epidemic is being reported worldwide (Centres for Disease Control and Prevention, 2017). Whilst these are generally adult diseases (such as heart disease, stroke, cancer, type 2 diabetes, obesity and arthritis), globally increasingly younger people are being diagnosed (Michaud & Suris, 2007). The ramifications of chronic disease and disability are often described in terms of the World Health Organisation (WHO) International Classification of Function framework (ICF) (impairment, function, ability) (Sherry 2014; Word Health Organization, 2002). The WHO framework describes how people live with a condition that compromises their capacity to fully function in their environment. The impact of chronic diseases and disability generally leads to long-

term sensory, cognitive and mobility impairments which manifest as restrictions in functional activities and employability (Mayosi et al., 2009; Howse, 2006). People living with disabilities are affected on a physical, psychological and social level (Lorenzo et al., 2015). Even though people living with disabilities are not necessary ill, the prevalence to fall ill is higher (Sherry, 2014). Disability not only affects the individual, but also the community and the economy of a country since people living with disabilities seek more health care than people without disabilities (World Health Organization, 2016). As the number of people living with diseases resulting in disabilities increase, the demand for rehabilitation services will also escalate (World Health Organization, 2017).

2.3 Disability and rehabilitation

Rehabilitation is defined by the WHO as a process that aims to enable people living with disabilities to reach and restore their highest level of function (World Health Organization, 2017). Rehabilitation therefore assists people living with disabilities to be more independent, to maintain their abilities and to enhance their quality of life (World Health Organization, 2017). Effective rehabilitation may also lead to return to work, thereby also alleviating the burden on the economy (Van den Broeck, 2016). It is therefore essential that every person living with a disability has the opportunity to access quality rehabilitation. For this reason the WHO initiated a call, the WHO Rehabilitation 2030 call, to stress the importance of the growing requirement for rehabilitation and to concentrate worldwide action towards reinforcement of rehabilitation in every health system (World Health Organization, 2017). Rehabilitation therefore forms a crucial part of the holistic approach to relieve the burden of disability (Van den Broeck, 2016) especially in countries where the burden of disability has the greatest impact.

Rehabilitation is a complex and person-specific development (Sherry, 2014). It is recommended that rehabilitation should be conducted in a multidisciplinary team which can include physiotherapist, occupational therapist, dietician, speech, language and hearing therapist, podiatrists, audiologists, social worker, psychologist,

pharmacist and nurses (Sherry, 2014). When rehabilitation is done by a team, a holistic approach is used which will assure that every aspect of treatment is covered (Visagiel & Schneider, 2014). Rehabilitation is more comprehensive and affective when conducted in a team approach and a patient will enjoy the benefits of rehabilitation sooner (Visagiel & Schneider, 2014). The team members do not only always have to play a curate roll, but they can also assist in expanding preventative and promotive services (Visagiel & Schneider, 2014).

2.4 Primary health care and rehabilitation

Primary health care (PHC) has been determined as the basic level of healthcare (Kautzkyi & Tollmani, 2008). According to the WHOs Guidelines on Community-based Rehabilitation, the current “gold-standard” recommendation for rehabilitation is that it should be as accessible in developing as well as in developed countries (Sherry, 2014). Essentially, rehabilitation should form part of PHC (Kautzkyi & Tollmani, 2008) and the WHO aims that rehabilitation should be accessible for all (World Health Organization, 2017), no matter where the person lives.

Rehabilitation forms a vital part of the preventative, promotive and curative pillars of health care (Sherry, 2014). Prevention can be done primary through reducing the patients risk and preventing onset of any disease, secondary after the onset of the disease to prevent further complications and tertiary to aim to reduce the effect on the patients’ health and participation (Sherry, 2014). The curative pillar ensures that the impairment from the disease is actively remediated (Sherry, 2014; Kautzkyi & Tollmani, 2008). Promotion can be done continually through self-management and participation (Sherry, 2014).

2.5 Primary health care and rehabilitation in South Africa

In South Africa, PHC has been determined as the basic level of healthcare that is universally accessible to everyone in the community and is affordable (Kautzkyi & Tollmani, 2008). The community healthcare centre, or clinic, is typically the first place where people living with disabilities, together with their families and/or caregivers, meet the healthcare team (Department of Health, 2000). PHC centres therefore focus more on the health of the families and the communities as a whole, rather than just the individual (World Health Organization, 2016). Through PHC settings, the burden of disabilities in the communities has the greatest chance of being addressed successfully and potentially be decreased (Van Geertruyden, Alberts, Modjadji, Meuleman, Fraeyman & Bastiaens, 2015).

However, since a large proportion of the South African population is affected by poverty and most parts of the country are rural (Statistics South Africa, 2015), it is often challenging for people living with disability to access essential health rehabilitation services at PHC level (Bongani & Benatar, 2014; Kautzkyi & Tollmani, 2008). Coupled with the shortages of healthcare settings and health care workers, there is an inadequate distribution of resources across the country (Kautzkyi & Tollmani, 2008). Furthermore, higher prevalence and more complex diseases such as the HIV/AIDS and TB pandemics in South Africa in the last 20 years have particularly burdened the public health care system, attracting the most focus from government and society (Kautzkyi & Tollmani, 2008). There has been little opportunity to shift the focus required onto rehabilitation, in order to deal with the increasing burden of non-communicable chronic diseases (World Health Organization, 2011). Therefore, despite the fact that rehabilitation should be provided at PHC level and be accessible to all in need, people with disabilities within poorer communities are often neglected (Department of Health, 2000).

In South Africa and other low-to-middle income countries, people living with a disability typically experience physical, social and financial barriers in accessing rehabilitation (Lorenzo et al., 2015). This can be particularly challenging in rural

communities where services may be limited, and employment opportunities for people with disabilities may be scarce. In these environments, there are also various challenges in accessing PHC due to distances and uneven terrains (Lorenzo et al., 2015; Submission Towards The National Health Insurance, 2011) and the lack of reliable transport such as a vehicle or bus (Submission Towards The National Health Insurance, 2011).

In addition, when people with disabilities do arrive at a PHC setting, it may be closed or short staffed, or the waiting period for rehabilitation appointments may be up to several months, which limits efficient rehabilitation and delays positive outcomes (Visagiel & Schneider, 2014). Although there has been an increase in the presence of qualified rehabilitation therapists such as physiotherapists, occupational therapists and speech and language therapists at community level due to the implementation of the compulsory community service year (Erasmus, 2012), and more outreach programs have been put in place, there continues to be a shortfall of rehabilitation services and service delivery, due to the increase in disease burden and workforce shortages (Visagiel & Schneider, 2014).

In many instances, there are also limited resources for promotional material and assistive devices at these settings which impacts on effective service delivery (Visagiel & Schneider, 2014). The financial burden for people with disabilities is also increased since there may be additional travelling costs due to the need for assistance during the journey as well as the need to hire assistive devices such as wheelchairs should they not be provided one by the healthcare setting (Submission Towards The National Health Insurance, 2011).

In addition social burdens such as stigma and discrimination from the other community members are also experienced which discourages an individual from wanting to seek rehabilitation services (Submission Towards The National Health Insurance, 2011), thereby delaying rehabilitation. Lastly, the delay between referral from hospital to PHC rehabilitation, and the timing of the appointment is often

excessive, and many people living with disabilities are 'lost in the system' (Visagie & Swartz, 2016).

The need has therefore arisen, to ensure that every South African, living in any area, has access to the best possible form of rehabilitation at PHC level. It is essential therefore, especially in areas where resources are scarce, that ways are found to make healthcare services at PHC level, specifically rehabilitation, more available, not only to the people who need it, but also to their communities (Kautzkyi & Tollmani, 2008).

2.6 Why conduct this study?

This study's primary purpose is to ascertain logistics of methods required to extract data for the description of the intervention. It will the form as a baseline of a larger project which intends to investigate ways in which the clinical practice guidelines (CPGs) recommended interventions could be delineated into a more clinician-friendly format, for example a mobile application or a flipchart, which would make the implementation and comprehension by any clinician in any setting, especially at PHC level, easier and user friendly.

2.6.1 The role of evidence in clinical practice

The regular use of CPGs has been promoted as a way of improving care, and standardising clinical decisions and treatment (Kredo, Bernhardsson, Machingaidze, Young, Louw, Ochodo, Grimmer, 2016). CPGs are described as *'convenient ways of packaging evidence for clinical use'* (Treweek, Oxman, Alderson, Bossuyt, Brandt, Brozek, Davoli, Flottorp, Harbour, Hill, Liberati, Liira, Schünemann, Rosenbaum, Thornton, Vandvik & Alonso-Coello, 2013). Good quality CPGs result from systematic evidence reviews and an assessment of both the benefits and harms of alternative treatment options (Graham et al., 2011). However, CPGs often do not consider local contexts such as the resources available to the patients and clinicians, local practices and patient preference, as well as cultural beliefs that may also not be taken into consideration in either the research underpinning the CPGs, or in the CPG

writing process (Kredo et al., 2016; Department of Health, 2000). Furthermore, clinicians may find it difficult to interpret the recommendations made by CPGs and translate the evidence into their practice, in ways that benefit their patients (Sherry, 2014). One of the reasons given for this is that the interventions recommended in CPGs often lack detail, and sufficient description to easily replicate or adapt recommendations for individual clinical practice. There is thus a major barrier in delivering CPG-based rehabilitation to less privileged areas such as those found in South Africa (Van Geertruyde et al., 2015).

Because CPGs are essentially derived from existing literature, recommendations made in CPGs may fail to provide the detail required to enable them to be applied immediately in practice, particularly in rural and remote regions where there are workforce and resource shortages. Therefore, in addition to developing international standard integrated rehabilitation CPGs which specifically focus on effective delivery of rehabilitation at PHC level, there is a need for the description of the interventions in current CPGs to be evaluated and delineated so that these interventions can be easily replicated and contextualized in clinical practice within the required context.

Currently there are many CPGs available on different conditions for different professions and contexts. However, on closer examination of these CPGs it quickly becomes evident that the interventions recommended for specific conditions within these CPGs lack sufficient detail for easy replication by a clinician in any clinical practice setting. When looking at the randomised controlled clinical trials (RCTs), which provides the baseline evidence for most CPGs that deal with intervention, it is also found that the intervention's description lacks details and are inefficient for direct implementation and replication in clinical practice (Douet, Milne, Anstee, Habens, Young & Wright, 2013). Since the reproducibility of an intervention in a clinical setting forms a crucial part of adding value to research and ensuring evidence-based practice (Duet et al., 2013), there is a need to investigate ways in which the CPG recommended interventions could be delineated into a more clinician-friendly format such as a flipchart or mobile application which would be easy to comprehend and implemented by any clinician in any setting, especially at PHC level.

2.6.2 Osteoarthritis of the knee and rehabilitation

As a starting point, this project investigated a prevalent condition in the South Africa (SA) PHC settings, namely osteoarthritis (OA) of the knee. Knee OA can be seen as one of the leading causes that is adding to global diseases (Cross, Smith, Hoy, Nolte, Ackerman, Fransen, Bridgett, Williams, Guillemin, Hill, Laslett, Jones, Cicuttini, Osborne, Vos, Buchbinder, Woolf & March, 2014). Knee OA together with hip OA was recently ranked as the 11th highest contributor to global disability from 291 other conditions (Cross et al., 2014). Knee OA is more prevalent in woman than in men and mostly affects people above 60 years (Cross et al., 2014). This is a common condition treated by physiotherapists and occupational therapists at community levels (Allen, Oddone, Coffman, Datta, Juntilla, Lindquist, Walker, Weinberger & Bosworth, 2010), and one which can be managed well with rehabilitation principles. There are many different rehabilitation approaches for OA knee such as self-management programs, education, community or home exercise programs, assistive devices and orthotics, braces and footwear, patellar taping, weight-loss and dieting as well as cognitive behavioural pain coping therapy (Meneses, Goode, Nelson, Lin, Joron, Allen, Bennell, Lohmander, Rernandes, Hochberg, Underwood, Conaghan, Liu, McAlindon, Golightly & Hunter, 2016). If symptoms are disabling a patient and all non-pharmacological options together with pharmacological options has been exhausted, patients can be offered a referral to an orthopaedist for surgical options such as a total knee arthroplasty (Meneses et al., 2016).

However self-help and education were recently reported as being highly effective as an intervention in a systematic review, where a clinical algorithm was developed (Meneses et al., 2016). Self-help and education are commonly recommended in CPGs; however details on how this should be undertaken by patients or clinicians are unclear. Often a generic approach is reported using a ‘one-size-fits-all’ self-help and education intervention in anticipation that this will be locally contextualised. Information in booklets and hand-outs for patients to assist them in self-management is often an area that lacks detail (Duet et al., 2013). In settings such as the South African PHC, culture, language, tribal beliefs and family expectations are critical contextual concerns that may impact on the effectiveness of PHC interventions of self-help and education (Lorenzo et al., 2015; Kautzkyi & Tollmani, 2008). It is

therefore likely that the 'one-size-fits-all' self-help and education interventions described in CPGs may be difficult to reproduce clinically in the heterogeneous PHC settings found in South Africa and other similar countries. The study therefore focused on adults with knee OA, and self-help and education interventions reported in CPGs consulting more recent RCTs. A standard evaluation approach was taken, using a recently-published checklist, the Template for Intervention Description and Replication Checklist (TIDieR) tool, to assess elements of rehabilitation interventions used (Hoffmann, Glasziou, Boutron, Milne, Perera, Moher, Altman, Barbour, Macdonald, Johnston, Lamb, Dixon-Woods, McCulloch, Wyatt, Chan & Michie, 2014). The study will therefore aim to evaluate the detail of descriptions of physiotherapy rehabilitation interventions, specifically self-help and education as management, of adults with specifically knee OA as reported in CPGs. Ensuring the reproducibility of the studies will increase the validity for use in evidence based practice.

CHAPTER 3

METHODOLOGY

3.1 Introduction

The following chapter details the methodology used in the main study of this project. A summary can be seen in Figure 1 at the end of the chapter. The study has been exempted from ethics (see *Appendix A*).

3.2 Research Question

Are the descriptions of physiotherapy rehabilitation interventions of self-help and education for people with knee osteoarthritis (OA) reported in clinical practice guidelines (CPGs) (and randomised controlled clinical trials (RCTs) detailed enough to reproduce in clinical practice for the South African primary health care (PHC) contexts?

3.3 Study Aim

This study aims to evaluate the descriptions of physiotherapy rehabilitation interventions of self-help and education for people with knee OA in CPGs and more recent RCTs, in terms of the detail provided, and how readily they could be replicated in clinical practice. It would serve as a baseline to a larger project investigating the application of CPGs in more clinician friendly ways.

3.4 Objectives

The objectives of this review are to:

1. Identify the most recent and the highest quality international CPGs for community based rehabilitation for adults living with knee OA.

2. Retrieve the RCTs that were used to underpin the evidence base on self-help and education used in the CPGs for knee OA.

3. Conduct a search in computerized bibliographic databases for the recent RCTs published after the CPGs' release date on self-help and education as a rehabilitation treatment for knee OA.

4. Critically appraise the quality of the RCTs (found in the CPGs and in the databases) on self-help and education as a rehabilitation treatment for OA making use of a critical appraisal tool.

5. Assess/evaluate and describe the interventions as defined in the included RCTs (found in the CPGs and in the databases) for self-help and education as a rehabilitation treatment for knee OA using the TIDieR tool.

6. To summarize any gaps in the ways that RCTs describe self-help and education for knee OA.

7. Discuss how the gaps identified in the descriptions of interventions provided in the included RCTs may constrain replication in clinical practice and also in the South African PHC context.

3.5 Criteria for considering studies

3.5.1 Criteria for inclusion and exclusion of CPGs

3.5.1.1 Inclusion criteria

Types of CPGs:

- CPGs for knee OA reporting on self-help and education as conservative management.
- Only English literature will be included.
- All CPGs published in international guideline clearing houses in the last five years from close off date (July 2016) (thus the search commenced January

2012). The close-off date matched the time constraints of this Masters degree.

Types of participants:

- Adult males and female individuals who suffer from knee OA at the time of the study (adults are considered to be older than 18 years).

3.5.1.2 Exclusion criteria

Types of CPGs

- CPGs with only surgical or pharmacological interventions.
- CPGs published before January 2012.

Types of participants

- Age younger than 18 years
- Animals
- Conditions other than OA.
- OA of joints other than the knee joint.

3.5.2 Criteria for inclusion and exclusion of RCTs

3.5.2.1 Inclusion criteria

Types of studies:

- Only RCTs focusing on self-help and education will be included in the review.
- RCTs published in English will be included in this review.
- All articles published in the available databases from January 2012 until May 2017 will be considered.

- RCTs which scored at least 5/10 on the PEDro Scale, to exclude poor quality articles (< 5/10) that may lead to biased methods or findings.

Types of participants:

- Adult males or females who suffer from knee OA (adults older than 18 years of age).

Types of interventions:

- patient self-management
- self-help
- self-care
- patient education
- education
- decision aids and materials
- patient leaflet
- patient information
- information

3.5.2.2 Exclusion criteria

Types of studies

- All articles scoring below 5/10 on the PEDro scale will not be considered for this review, to ensure credibility of research.
- Study protocols

Types of participants

- Animals
- Conditions other than OA.
- OA of all other joints affected than the knee.

3.6 Search Strategy

The RCT data collection process is described in detail in Chapter 4 and is summarised here for clarity.

- RCTs reported in the included CPGs sections on self-help and education were identified from the relevant CPGs reference lists. Where systematic reviews formed the evidence source underpinning CPGs recommendations, their reference lists were searched for the component RCTs. The RCTs references were collated into a dataset and the systematic review was discarded.
- An independent, additional literature search (in two electronic databases) was undertaken to update this dataset with more recent RCTs, by searching for relevant RCTs published since the last date of literature inclusion of the most recent CPGs.

3.6.1 Search strategy for CPGs

The search process was conducted by the principle reviewer (and double checked by an independent reviewer) and every step of the process was recorded. Computerised clearing houses that provide CPGs were accessed through the World Wide Web to conduct the search for CPGs. The clearing houses searched were the following: *Scottish International Guideline Network (SIGN), National Institute for Health and Excellence (NICE), New Zealand Guidelines Group (NZGG), National Health and Medical research Council (NHMRC),* and *National Guideline Clearing House (NGCH).*

The key search terms are described in Table 1.

Table 1: Search terms in guideline clearing houses

Search Terms:
1. Knee Osteoarthritis
2. #1 AND guideline
3. #1 AND algorithm
4. #1 AND pathway

3.6.2 Search Strategy for RCTs

The search process was conducted by the principal researcher and every step of the process was recorded. Due to the search only being an update of the RCTs found in the CPGs, only two databases was search. The two different computerised bibliographic databases were accessed through the University of Stellenbosch library services to conduct this search. These databases were: *Pubmed* and *PEDro*.

The key search terms included: *patient self-management, self-help, self-care, patient education, education, decision aids and materials, patient leaflet, patient information, information* and *knee osteoarthritis.*

According to the function of each database, two separate search strategies were developed to search each database:

Pubmed

Limits applied to the database:

Type of search:	Advanced search
Publication dates:	2012 until May 2017
Publication types:	Clinical trial
	Randomized controlled trial
	Patient hand-out
MeSH Terms:	"knee osteoarthritis "[Mesh]
	"self-care"[Mesh] [Replacing: self-management, self-help]
	"patient education"[Mesh] [replacing education]
	“decision aids” [Mesh]
	“decision materials” [Mesh]

Table 2: Search terms used in Pubmed

Search Terms:
1. " Knee Osteoarthritis "[MeSH major topic)
2. #1 AND "self-care"[Mesh]
3. #1 AND "patient education"[Mesh]
4. #1 AND “decision aids” [Mesh]
5. #4 AND “decision materials” [Mesh]
6. #1 AND patient leaflet
7. #1 AND information

PEDro

Type of search: Advance Search

Publication dates: 2012 until 2017

Method: Trial

Table 3: Search Terms used in PEDro

Search Terms:
1. "Knee Osteoarthritis"
2. #1 AND self-management
3. #1 AND self help
4. #1 AND self-care
5. #1 AND patient education
6. #1 AND education
7. #1 AND materials
8. #1 AND patient leaflets
9. #1 AND patient information
10. #1 AND information

3.7 Level of Evidence and Methodological Appraisal

3.7.1 Level of Evidence for the studies

The National Health and Medical Research Council (NHMRC) Hierarchy of Evidence (Table 4) was used to categorise the included studies (both CPGs and RCTs included) (National Health and Medical Research Council, 2000).

Table 4: Designation of levels of evidence (NHMRC, 2000)

Level of evidence	Study design
I	Evidence obtained from a systematic review of all relevant randomized controlled trials.
II	Evidence obtained from at least one properly-designed randomized controlled trial.
III-1	Evidence obtained from well-designed pseudo-randomized controlled trials (alternate allocation or some other method).
III-2	Evidence obtained from comparative studies with concurrent controls and allocation not randomised, cohort studies, case-control studies, or interrupted time series with a control group.
III-3	Evidence obtained from comparative studies with historical control, two or more single arm studies, or interrupted time series without a parallel control group.
IV	Evidence obtained from case series (post-test or pre-test/post-test).

3.7.2 Methodological Appraisal of CPGs and RCTs

3.7.2.1 Methodological appraisal of CPGs

The International Centre for Allied Health Evidence (iCAHE) Guideline Quality Check List *(Appendix B)* appraisal tool will be used to assess the methodological quality of the selected CPGs (International Centre for Allied Health Evidence Guideline Quality Check List, 2014; Treweek et al., 2013). The iCAHE scoring system is a simple, efficient method of appraising the methodological quality of a clinical guideline which is oriented to busy end-users. The iCAHE system was applied by two researchers independently to determine the methodological quality of each CPG. Afterwards they

discussed their findings and used consensus to identify the CPGs with the best methodological quality (Grimmer, Machingaidze, Kredo, Louw & Young, 2016; Grimmer, Dizon, Milanese, King, Beaton, Thorpe, Lizarondo, Luker, Kumar & Machokta, 2014).

3.7.2.1 Methodological Appraisal for RCTs

The methodological quality of the additional RCTs found after 2012 in the electronic databases as well as the RCTs that was used to compile the CPGs, was measured by making use of the PEDro scale (*Appendix C*). The PEDro scale was developed at the University of Maastricht to be used as a quicker means to determine the methodological quality of RCTs on the PEDro database (Verhagen, De Vet, De Brie, Kessels, Boers, Bouter & Knipschild, 1998). The PEDro scale, which is based on the Delphi list, consists of eleven criteria that measure a study's external validity (criteria 1), internal validity (criteria 2-9) and the statistical accuracy for interpretation purposes (criteria 10-11) (Verhagen et al., 1998). The effectiveness or clinical importance of a treatment technique should not be measured using the PEDro scale (Tooth, Bennett, McCluskey, Hoffmann, McKenna & Lovarini, 2005; Verhagen et al., 1998).

3.8 Data Extraction Method

The Template for Intervention Description and Replication Checklist (TIDieR) *(Appendix D)* tool was used for data extraction from the RCTs (Hoffmann et al., 2014). The TIDieR tool was developed to improve reporting of interventions in studies. It assists with improving the quality of the interventions and insures better descriptions leading to simplification of replication (Yamato et al., 2015). The synthesisation is also improved. The 12 items of the checklist is an extension to the CONSORT 2010 statement and the SPIRIT 2013 to provide further guidance for authors on key information included in clinical trials (Yamato et al., 2015). Data extraction was undertaken for each of the following aspects (Yamato et al., 2015):

- *Include the name of the intervention (Yes / No).*
- *Intervention rationale for essential elements (three elements each scoring 33.33%).*
- *Intervention materials and details about how to access them (four elements each scoring 25%).*
- *Description of the intervention procedures (two elements each scoring 50%).*
- *Details of intervention providers (four elements each scoring 25%).*
- *Mode of delivery of intervention (two elements each scoring 50%).*
- *Location of intervention delivery and key infrastructure (three elements each scoring 33.33%).*
- *Details about the number; duration, intensity, and dose of intervention sessions (five elements each scoring 20%).*
- *Details of any intervention tailoring (five elements each scoring 20%).*
- *Any intervention modifications throughout the study (two elements each scoring 50%).*
- *Details of intervention fidelity assessment (four elements each scoring 25%) with monitoring, and level achieved (Yes/No).*

Details to address each TIDieR element were extracted from the RCTs. 'Yes' scores were assigned where more than half of the elements for each TIDieR aspect was clearly described, and 'No' scores were assigned where there was no information provided on the element or less than half of the elements were described for each TIDieR aspect. 'Part' marks were assigned where the study provided some but not all details on each element.

3.9 Data Analysis Handling and Method

The RCTs was evenly divided between the researchers with each RCT being reviewed by two researchers. The two researchers responsible for a RCT independently extracted and analyse data followed by a comparison of their findings. If consensus about the data analysis was not reached, the two researchers presented their differences to a third researcher. The third researcher considered

both arguments and gave her own opinion regarding the data analysis to reach consensus.

The TIDieR checklist for each trial was completed using an electronic, stand-alone access database. The data was then exported into a Microsoft Excel spread sheet for data analysis. In the event that data is not comparable, a summary was given in a narrative form.

3.10 The constrains of replication in clinical practice

Effective rehabilitation for OA knees for patients in South Africa (SA) PHC contexts needs to consider specific issues of local culture, language, environment, imposts on patients seeking rehabilitation, literacy and cultural beliefs about OA knee. (Lorenzo et al., 2015; Kautzkyi & Tollmani, 2008). The TIDieR findings were reconsidered within the contexts of PHC in South Africa, using a purpose-built checklist. An additional score was provided regarding whether the intervention as described in the included RCT, could be implemented into local settings without change.

Checklist *(developed by discussion within team configuration)*

- Can the intervention be delivered by physiotherapists in PHC settings anywhere in South Africa (if not, why not)?
- Could the intervention be adopted by patients in his or her own environment (if not why not)?

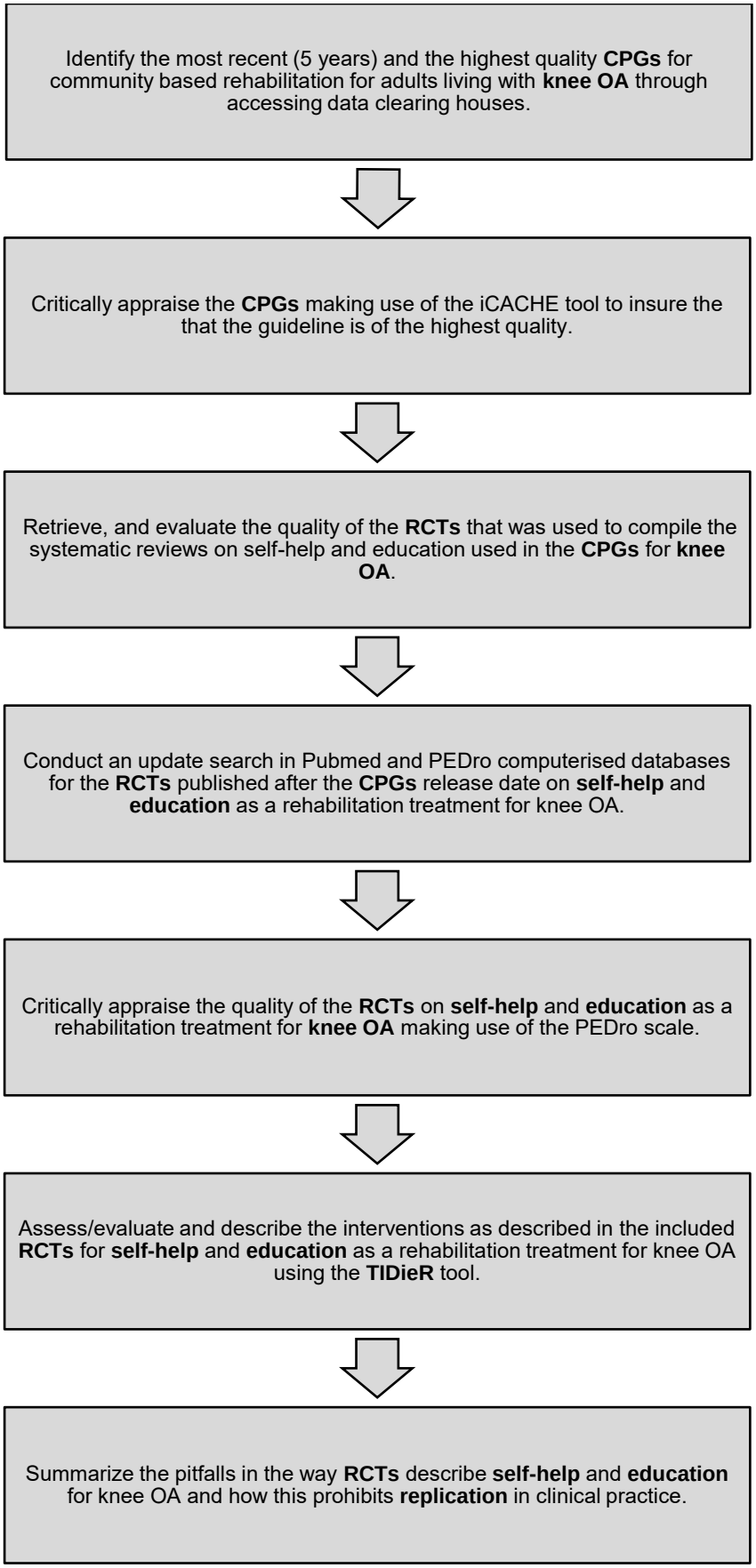

Figure 1: Flowchart Illustrating Complete Study Procedure

CHAPTER 4

RESULTS

4.1 Introduction

The primary aim of the current study was to evaluate the descriptions of physiotherapy rehabilitation interventions of self-help and education for people with knee osteoarthritis (OA) in clinical practice guidelines (CPGs) and more recent randomised controlled clinical trials (RCTs), in terms of the detail provided, and how readily they could be replicated in clinical practice. The following chapter presents the results of the study.

4.2 Search Results and Description

4.2.1 Search Results for CPGs

4.2.1.1 Titles

Using the search terms provided in Table 1, a total of five initial guidelines were found during a comprehensive search of the selected data clearing houses. The search results for the study title inclusion and exclusion is summarized in Table 5.

Table 5: Title inclusion and results for CPGs

Database	Total hits	Excluded titles within clearing houses (Irrelevant topics, animals)	Included titles within clearing houses.	Duplicates between clearing houses	Included titles between clearing houses
Scottish International Guideline Network (SIGN)	14	14	0	1	5
National Institute for Health and Excellence (NICE)	3	2	1		
New Zealand Guidelines Group (NZGG)	5	5	0		
National Health and Medical research Council (NHMRC)	12	12	0		
National Guideline Clearing House (NGCH)	21	17	4		
Osteoarthritis Research Society International (OARSI)	30	29	1		

4.2.1.2 Dates and full CPGs

Five CPGs were considered from the initial included titles across the different data clearing houses. However, after further inspection of the dates and full CPGs, three CPGs (American Academy of Orthopaedic Surgeons, 2013; Jevsevar, Brown, Jones, Matzkin, Manner, Mooar, Schousboe, Stovitz, Sanders, Bozic, Goldberg, Martin, Cummins, Donnelly, Woznica & Gross, 2013; Loew, Brosseau, Wells, Tugwell, Kenny, Reid, Maetzel, Huijbregts, McCullough, De Angelis, Coyle & the Ottawa Panel, 2012) were excluded due to only including surgical or pharmacological interventions, published before January 2012 and not reporting on adults suffering from knee OA. Only two CPGs (National Clinical Guideline Centre, 2014; McAlindon, Bannuru, Sullivan, Arden, Berenbaum, Bierma-Zeinstra, Hawker, Henrotin, Hunter, Kawaguchi, Kwoh, Lohmander, Rannou, Roos, & Underwood, 2014) were found eligible.

4.2.2 Search results of RCTs from SRs included in CPGs

4.2.2.1 Titles

A total of five systematic reviews (SRs) and/or Meta-analysis were found in the CPGs for self-help and education with two SRs overlapping resulting the inclusion of three SRs (Chodosh, Morton, Mojica, Maglione, Suttor, Hilton, Rhodes & Shekelle, 2005; Superio-Cabuslay, Ward & Lorig, 1996; Dua, Yuan, Niao, Chu, Qiu & Qian, 2011). A total of 54 initial titles were found in the three SRs. The search results for the study title inclusion and exclusion is summarized in Table 6.

Table 6: Title inclusion for RCTs in SRs

CPGs	Total RCTs	Excluded titles within CPGs (Irrelevant topic)	Included titles within CPGs	Duplicates between SRs/MAs	Included titles between CPGs
NICE	30	5	25	6	37
OARSI	24	4	20		
Total	54	9	43		

4.2.2.2 Abstracts and Full text articles

Thirty-seven abstracts were considered from the initial search for RCTs in the two CPGs. However, after further inspection of the abstracts, only 27 abstracts were found to be potentially eligible and the full text articles of these abstracts were retrieved. On review of the full text articles, it was found that 19 articles did not meet the inclusion criteria for this review due to either including other conditions than OA or other joints that the knee. Eight RCTs (Hurley, Walsh, Mitchell, Nicholas, & Patel, 2012; Ravaud, Flipo, Boutron, Roy, Mahmoudi, Giraudeau & Phamassistant, 2009; Hurley, Walsh, Mitchell, Pimm, Patel, Williamson, Jones, Dieppe & Reeves, 2007; Yip, Sit, Fung, Wong, Chong, Chung & Ng, 2007; Nuñez, Nuñez, Segur, Macule, Quinto, Hernandez & Vilalta, 2006; Victor, Triggs, Ross, Lord & Axford, 2005; Keefe, Caldwell, Williams, Gil, Mitchell, Robertson, Martinezb, Nunley, Beckham & Helms, 1990; Goeppinger, Arthur, Baglioni, Brunk & Brunner, 1989) were therefore included from the CPGs. The results of the search strategy is summarised in Figure 2 and includes the titles after the duplicates were eliminated and the abstracts, as well as the full text articles, were retrieved.

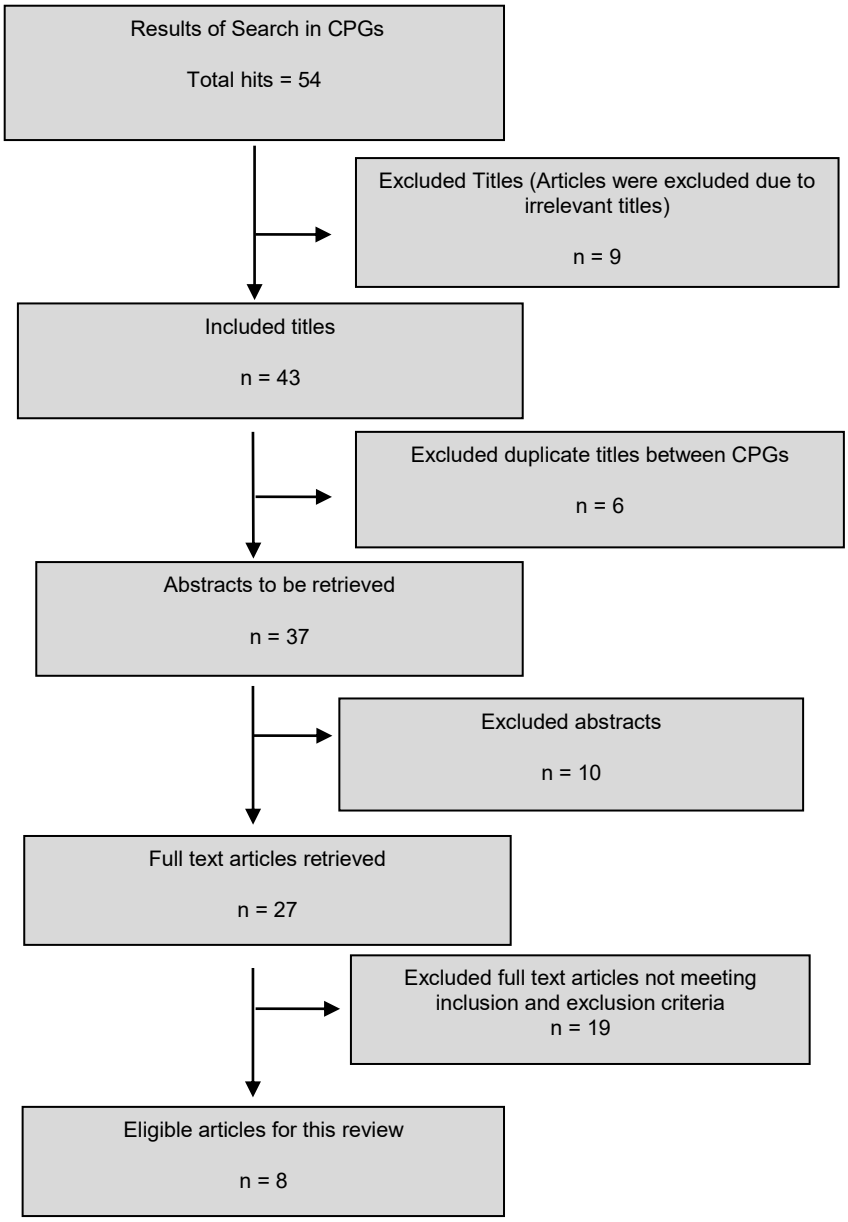

Figure 2: Results of search done in CPGs

4.2.3 Search results for RCTs in databases

4.2.3.1 Titles

Using the search terms provided in Tables 2 and 3, a total of 293 initial titles were found during a comprehensive search of the selected electronic databases. The search results for the study title inclusion and exclusion is summarized in Table 7.

Table 7: Title inclusion for RCTs in databases

Database	Total hits	Excluded titles within database	Included titles within database	Duplicates between databases	Included titles between databases
Pubmed	186	163	23	27	15
PEDro	107	88	19		
Total	293	251	42		

4.2.3.2 Abstracts and Full text articles

Fifteen abstracts were considered from the initial included titles across the two different databases. However, after further inspection of the abstracts, only six abstracts were found to be potentially eligible and the full text articles of these abstracts were retrieved. On review of the full text articles, it was found that two articles did not meet the inclusion criteria for this review due to either not meeting the PEDro score of five out of ten, including conditions other than OA and joints other than the knee. Four articles (Hinman, Wrigley, Metcalf, Campbell, Paterson, Hunter, Kasza, Forbes & Bennell, 2016; Da Silva , De Melo, Do Amaral, Caldas, Pinheiro, Abre & Brito, 2015; Coleman, Briffa, Carroll, Inderjeeth, Cook & McQuade, 2011; Kao, Wu, Tsai, Chang & Wu, 2012) were therefore included in this review. The results of the search strategy is summarised in Figure 3 and includes the titles after the duplicates were eliminated and the abstracts, as well as the full text articles, were retrieved.

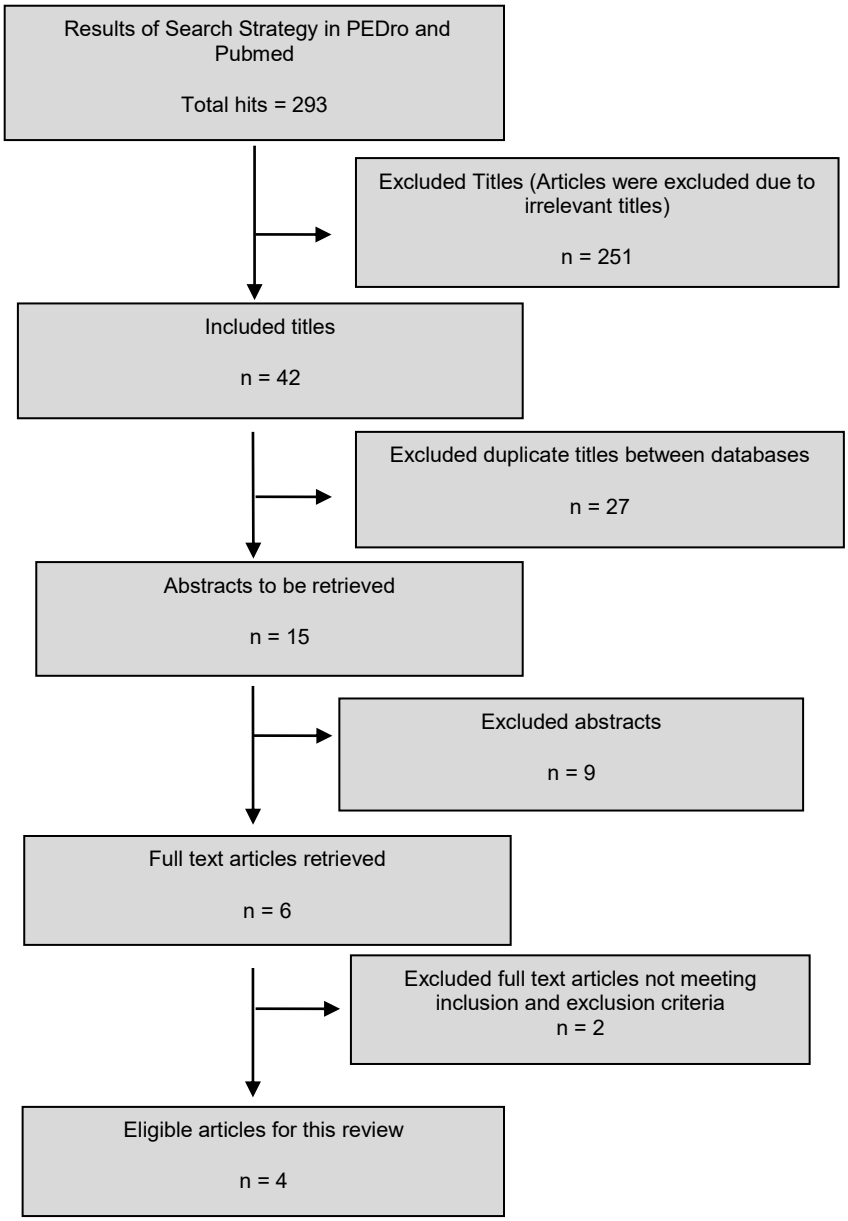

Figure 3: Results of search strategy of databases: Pubmed and PEDro

Therefore following exclusion's, two CPGs were relevant to this search, from which eight RCTs were identified as relevant. An additional four RCTs were identified in the update search.

4.3 Evidence Hierarchy

The 12 articles found to be appropriate to include in this review were all RCTs. All the included articles were therefore classified as Level II evidence according to the

Hierarchy of Evidence set forth by the National Health and Medical Research Council (NHMRC 2000).

4.4 Methodological Appraisal

4.4.1 Quality scores CPGs:

The International Centre for Allied Health Evidence (iCAHE) scores for the NICE (National Clinical Guideline Centre, 2014) CPG were 13/14 and the OARSI (McAlindon, et al., 2014) were 12/14. Table 8 provides a summary of each CPGs score.

Table 8: Scores according to the iCAHE criteria

iCAHE	NICE	OARSI
1. Is the guideline readily available in full text?	Y	Y
2. Does the guideline provide a complete reference list?	Y	Y
3. Does the guideline provide a summary of its recommendations?	Y	Y
4. Is there a date of completion available?	N	N
5. Does the guideline provide an anticipated review date?	Y	N
6. Does the guideline provide dates for when literature was included?	Y	Y
7. Does the guideline provide an outline of the strategy they used to find underlying evidence?	Y	Y
8. Does the guideline use a hierarchy to rank the quality of the underlying evidence?	Y	Y
9. Does the guideline appraise the quality of the evidence which underpins its recommendations?	Y	Y
10. Does the guideline link the hierarchy and quality of underlying evidence to each recommendation?	Y	Y
11. Are the developers of the guideline clearly stated?	Y	Y
12. Does the qualifications and expertise of the guideline developer(s) link with the purpose of the guideline and its end users?	Y	Y
13. Are the purpose and target users of the guideline stated?	Y	Y
14. Is the guideline readable and easy to navigate?	Y	Y
TOTAL SCORE	**13/14**	**12/14**

Key: Y=Yes; N=No

4.4.2 Quality scores for RCTs:

The methodological quality of the twelve included RCTs found from the computerised search together with the RCTs from the CPGs was assessed by the eleven-item PEDro scale. For the purpose of this review, criterion 1 (eligibility criteria were previously specified) was not used to calculate the PEDro score but was retained so that the researchers could identify whether or not eligibility criteria were reported in the articles. The total maximum score an article could therefore obtain on the PEDro scale was ten. All the articles scored between five out of ten and eight out of ten, with an average score of six out of 10. Three articles (Victor et al., 2005, Keefe et al., 1990; Groeppinger et al., 1989) scored below 5/10 and were therefore excluded. Table 9 provides a summary of each included article's PEDro score.

Table 9: Scores according to the PEDro criteria

PEDro criteria	Hinman et al., 2016	Da Silva et al., 2015	Coleman et al., 2012	Hurley et al., 2012	Kao et al., 2011	Ravaued et al., 2009	Hurley et al., 2007	Yip et al., 2007	Nuñez et al., 2006
1. Eligibility criteria were specified	Y	Y	Y	Y	Y	Y	Y	Y	Y
2. Subjects were randomly allocated	Y	Y	Y	Y	Y	Y	Y	Y	Y
3. Allocation was concealed	Y	Y	Y	N	N	Y	N	N	N
4. The groups were similar at baseline	N	Y	Y	Y	N	Y	Y	Y	Y
5. There was blinding of all subjects	Y	N	N	N	N	N	Y	N	N
6. There was blinding of all therapists	N	N	N	N	N	N	N	N	N
7. There was blinding of all assessors	Y	Y	Y	Y	Y	Y	Y	N	Y
8. Measures of at least one key outcome	Y	N	Y	Y	Y	Y	Y	N	N
9. All subjects for whom outcome measures were available received the treatment or control condition as allocated	Y	N	Y	Y	Y	N	Y	Y	N
10. The results of between-group statistical comparisons are reported for at least one key outcome	Y	Y	Y	Y	Y	Y	Y	Y	Y
11. The study provides both point measures and measures of variability for at least one key outcome	Y	Y	Y	Y	Y	Y	Y	Y	Y
Total score	**8/10**	**6/10**	**8/10**	**7/10**	**6/10**	**7/10**	**8/10**	**5/10**	**5/10**

Note: Eligibility criteria item (item 1) does not contribute to total score

Key: Y=Yes; N=N

4.5 Description of TIDieR Checklist

The Template for Intervention Description and Replication (TIDieR) checklist was applied to the remaining nine RCT (Hinman et al., 2016; Da Silva et al., 2015; Coleman et al., 2012; Hurley et al., 2012; Kao et al., 2011; Ravaued et al., 2009; Hurley et al., 2007; Yip et al., 2007; Nuñez et al., 2006) from 2006 to 2016. As described in the data extraction method section, data extraction was done according to the TIDieR intervention aspects:

- *Include the name of the intervention (Yes / No.)*
- *Intervention rationale for essential elements (three elements each scoring 33.33%).*
- *Intervention materials and details about how to access them (four elements each scoring 25%).*
- *Description of the intervention procedures (two elements each scoring 50%).*
- *Details of intervention providers (four elements each scoring 25%).*
- *Mode of delivery of intervention (two elements each scoring 50%).*
- *Location of intervention delivery and key infrastructure (three elements each scoring 33.33%).*
- *Details about the number; duration, intensity, and dose of intervention sessions (five elements each scoring 20%).*
- *Details of any intervention tailoring (five elements each scoring 20%).*
- *Any intervention modifications throughout the study (two elements each scoring 50%).*
- *Details of intervention fidelity assessment (four elements each scoring 25%) with monitoring, and*
- *Description of Intervention Fidelity level achieved (Yes/No).*

A score was given for level of completeness. ‘Yes’ scores were assigned where more than half of the elements for each TIDieR aspect were clearly described. ‘No’ scores were assigned where there was no information provided on the element or less than half of the elements were described for each TIDieR aspect. A summary of the TIDieR results can be seen in Table 10. ‘Part’ marks were assigned where the

study provided some but not all details on each element and a score out of the total of each element was given with the percentage. A summary of the results for each element can be seen in table 11.

Table 10: Summary of TIDieR finding

TIDieR INTERVENTION ASPECTS	AVERAGE SCORE OF LEVEL OF COMPLETENESS
1. Name of the intervention.	n=7 (77.78%)
2. Intervention rationale for essential elements.	n=9 (100%)
3. Intervention materials and details about how to access them.	n=2 (22.22%)
4. Description of the intervention procedures.	n=8 (88.89%)
5. Details of intervention providers.	n=4 (44.44%)
6. Mode of delivery of intervention.	n=9 (100%)
7. Location of intervention delivery and key infrastructure.	n=0 (0%)
8. Details about the number, duration, intensity, and dose of intervention sessions.	n=8 (88.89%)
9. Details of any intervention tailoring.	n=1 (11.11%)
10. Any intervention modifications throughout the study.	n=0 (0%)
11. Details of intervention fidelity assessment, monitoring, and level achieved.	n=1 (11.11%)
12. Description of Intervention Fidelity Level Achieved.	n=9 (100%)

Table 11: Summary of each articles score on the TIDieR checklist

RCT	1.BRIEF NAME	2. WHY	3. WHAT	4. PRO-CEDURES	5. WHO PROVIDED	6. HOW	7. WHERE	8. WHEN and HOW MUCH	9. TAILORING	10. MODIFI-CATION	11. HOW WELL: PLANNED	12: HOW WELL: ACTUAL
	Yes / No	three elements each scoring 33.33%	four elements each scoring 25%	two elements each scoring 50%	four elements each scoring 25%	two elements each scoring 50%	three elements each scoring 33.33%	five elements each scoring 20%	five elements each scoring 20%	two elements each scoring 50%	four elements each scoring 25%	Yes/No
Hinman et al., 2016	1/1 = 100%	3/3 = 100%	3/4 = 75%	2/2 = 100%	1/4 = 25%	1/2 = 50%	1/3= 33.33%	2/5 = 40%	0/5 = 0%	0/2 = 0%	3/4 = 75%	1/1 = 100%
Da Silva et al., 2015	1/1 = 100%	2/3 = 66.67%	1/4 = 25%	2/2 = 100%	1/4 = 25%	2/2 = 100%	0/3 = 0%	5/5 = 100%	0/5 = 0%	0/2 = 0%	1/4 = 25%	1/1 = 100%
Coleman et al., 2012	1/1 = 100%	3/3 = 100%	1/4 = 25%	2/2 = 100%	2/4 = 50%	2/2 = 100%	1/3 = 33.33%	3/5 = 60%	0/5 = 0%	0/2 = 0%	2/4 = 50%	1/1 = 100%
Hurley et al., 2012	1/1 = 100%	3/3 =100%	1/4 = 25%	2/2 = 100%	2/4 = 50%	2/2 = 100%	1/3 = 33.33%	5/5 = 100%	2/5 = 40%	0/2 = 0%	1/4 = 0%	1/1 = 100%

Table 11: Summary of each articles score on the TIDieR checklist (continued)

Kao et al., 2011	1/1 = 100%	3/3 =100%	1/4 = 25%	1/2 = 50%	2/4 = 50%	2/2 = 100%	1/3= 33.33%	3/5 = 60%	0/5 = 0%	0/2 = 0%	1/4 = 25%	1/1= 100%
Ravaued et al., 2009	0/1 = 0%	3/3 = 100%	4/4 = 100%	2/2 = 100%	1/4 = 25%	2/2 = 100%	1/3= 33.33%	4/5 = 80%	3/5 = 60%	0/2 = 0%	1/4 = 0%	1/1= 100%
Hurley et al., 2007	1/1 = 100%	3/3 = 100%	1/4 = 25%	0/2 = 0%	1/4 = 25%	2/2 = 100%	1/3= 33.33%	3/5 = 60%	1/5 = 20%	0/2 = 0%	1/4 = 0%	1/1 = 100%
Yip et al., 2007	1/1 = 100%	3/3 = 100%	1/4 = 25%	2/2 = 100%	2/4 = 50%	2/2 = 100%	1/3= 33.3%	4/5 = 80%	0/5 = 0%	0/2 = 0%	1/4 = 0%	1/1 = 100%
Nuñez et al., 2006	1/1 = 100%	3/3 = 100%	1/4 = 25%	½ = 50%	1/4 = 25%	2/2 = 100%	1/3= 33.33%	5/5 = 100%	0/5 = 0%	0/2 = 0%	1/4 =0%	1/1 = 100%
Average part marks %	7/9 (77.78%)	2.89/3 (96.34%)	1.56/4 (39%)	1.56/2 (78%)	1.44/4 (36%)	1.89/2 (94.44%)	0.89/3 (29.63%)	3.78/5 (75.56%)	0.67/5 (13.33%)	0/2 (0%)	1.33/4 (33.25%)	9/9 (100%)

Table 12-24 indicates the individual part mark scores of each TIDieR aspect's element and also the example of the descriptions. Results are also displayed in Figure 4-23.

Table 12 contains the examples of the brief names or phrases. It is seen that the majority of the RCTs (77.78%) had a brief name or phrase for their intervention.

Table 12: Detailed description of Name of the Intervention

BRIEF NAME OR PHRASE OF INTERVENTION				
RCT	**Yes**	**No**	**TOTAL**	
Hinman et al., 2016	"Unloading Shoes for Self-management"		1	100%
Da Silva et al., 2015		"Group rehabilitation program"	0	0%
Coleman et al., 2012	"Osteoarthritis of the Knee Self-Management Program (OAK)"		1	100%
Hurley et al., 2012	"Enabling Self-Management and Coping of Arthritic Knee Pain Through Exercise (ESCAPE-knee pain)"		1	100%
Kao et al., 2011	"Taipei Osteoarthritis Program(TOAP)"		1	100%
Ravaued et al., 2009		"Standardised consultation"	0	0%
Hurley et al., 2007	"Enabling Self-management and Coping with Arthritic Knee Pain through Exercise (ESCAPE-knee pain)"		1	100%
Yip et al., 2007	"Arthritis self-management programmes (ASMP)"		1	100%
Nuñez et al., 2006	"Therapeutic education and functional re-adaptation (TERF)"		1	100%
AVERAGE SCORE OF DESCRIPTION			7/9	77.78%

High levels of completeness can be found for the aspect '*intervention rationale for essential elements'* (scoring 96.34%). One RCT (Da Silva et al., 2015) lacked information on the element *'goal essential to the intervention*'.

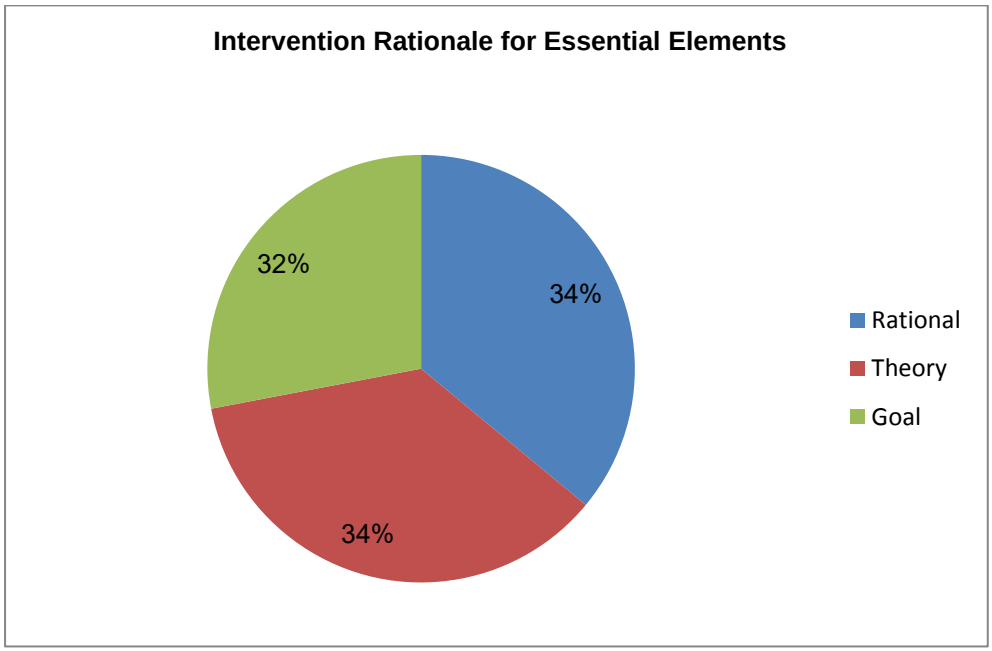

Figure 4: Pie chart on Intervention Rationale for Essential Elements

Table 13: Detailed description of Intervention Rationale for Essential Elements

WHY: Intervention Rationale for Essential Elements					
RCT	**Rational**	**Theory**	**Goal**	**TOTAL**	
Hinman et al., 2016	"We hypothesized that unloading shoes would reduce pain and improve physical function after 6 months compared with conventional walking shoes."	"Wearing shoes increases medial knee load compared with being barefoot so recent research has focused on developing novel "unloading shoes" for persons with knee osteoarthritis to reduce medial knee load. Unloading shoes with soles that are stiffer laterally than medially significantly reduce medial knee loads via changes in foot and ankle biomechanics compared with shoes with conventional soles of uniform stiffness."	"The aim of this study was to evaluate the efficacy of unloading walking shoes in alleviating knee osteoarthritis symptoms."	3/3	100%
Da Silva et al., 2015	"To be effective, the physical activity program should include patient counselling and education in order to promote positive changes in lifestyle, such as increased daily physical activity and understanding and coping with problems and limitations."	"We hypothesized that this integrated group rehabilitation program would limit pain and improve quality of life and function in patients with knee OA as compared with those receiving no exercise intervention."	N	2/3	66.67%

Coleman et al., 2012	"It is a disease-specific OA self-management education program designed for delivery by health care professionals. Its theoretical framework uses Social Cognitive."	"The OA knee program was designed as a community-based SM education program that aims to improve pain, function and quality of life and to empower people to address these preferences with the support of health care professionals who have expertise in this area."	"In this study, we sought to determine whether a disease specific self-manage programs for people with osteoarthritis of the knee (the OA knee program), implemented by health care professionals, would achieve and maintain clinically meaningful improvements in health-related outcome compared with a control group."	3/3	100%
Hurley et al., 2012	"The few studies with long-term. Follow up have not found sustained clinical benefits and do not include an economic evaluation. Health care commissioners are reluctant to provide interventions without evidence of sustained benefits, so people may be deprived of potentially useful treatment."	"We hypothesized that these short-term clinical and cost benefits would be lost over time."	"Designed to improve function by integrating exercise, education, and self-management strategies to dispel inappropriate health beliefs, alter behaviour, and encourage regular physical activity."	3/3	100%
Kao et al., 2011	"In addition, although self-management programs have been proven to be effective in various countries such as United States of America, United Kingdom, and Hong Kong, such programs need to be specific to a local culture and in tune with the ethnic group."	"Self-management education program are designed to allow people with chronic conditions to take an active part in the management of their own condition."	"The aim of this study was to evaluate the effectiveness of the TOAP intervention on patients who suffer from knee OA."	3/3	100%
Ravaued et al., 2009	"Recommendations are difficult to implement because this is a complex intervention that is time consuming for physicians and supposes a high level of understanding and adherence by the patient."	"Our intervention is drawn in part from an intervention intended to limit the number of actions per visit to a physician and has previously been tested in randomised controlled trial."	"To overcome these problems, we aimed to develop an intervention that would be easy to implement for physicians and that could improve patients' adherence."	3/3	100%
Hurley et al., 2007	"Combining exercise and self-management might enhance their separate benefits, but few people will benefit if this produces complex, unworkable rehabilitation programs."	"Our primary hypothesis was that participation in ESCAPE knee pain would improve functioning better than continuing usual primary care. A subsidiary hypothesis was that rehabilitation would be equally effective whether delivered to individuals or groups of people."	"As more people live longer and patterns of incidence change, safe, effective, and efficient interventions that improve functioning and can be delivered to the large numbers of people will be needed."	3/3	100%
Yip et al., 2007	It was designed to give participants skills they could use to optimize their ability to manage their condition.	The programme focused on teaching participants how to cope with and manage common knee OA consequences, such as arthritis pain, fatigue, daily activity limitations and stress.	The aim of the study was to assess the effect of an adapted arthritis self-management programme with an added focus on exercise practice among osteoarthritic knee sufferers.	3/3	100%
Nuñez et al., 2006	"The objective of the present study was to evaluate the effect of a program of therapeutic education and functional preadaptation on health related quality of life in patients diagnosed with OA on a waiting list for total knee replacement."	"The program was based on theories of social learning and self-management, and carried out using active learning strategies."	"The intervention group followed a program for patients with musculoskeletal diseases involving the lower limbs, designed to improve pain and functional disability and to increase patient disease self-management."	3/3	100%
AVERAGE SCORE OF DESCRIPTION				2.83/3	96.34%

Key: N=No

As seen in table 14, the description of the aspect *'physical materials and how to accesses them'*, are 61% incomplete with element *'materials used in training for the intervention providers'* lacking the most description. Only four of the nine RCTs provided links where the materials can be accessed. Only one RCT (Ravaued et al., 2009), reported on all the elements. Examples of the intervention materials provided to participants are shoes, printed or written information, pedometer, booklets, diaries or tapes. DVDs, exercise equipment and audio tapes were used during intervention delivery.

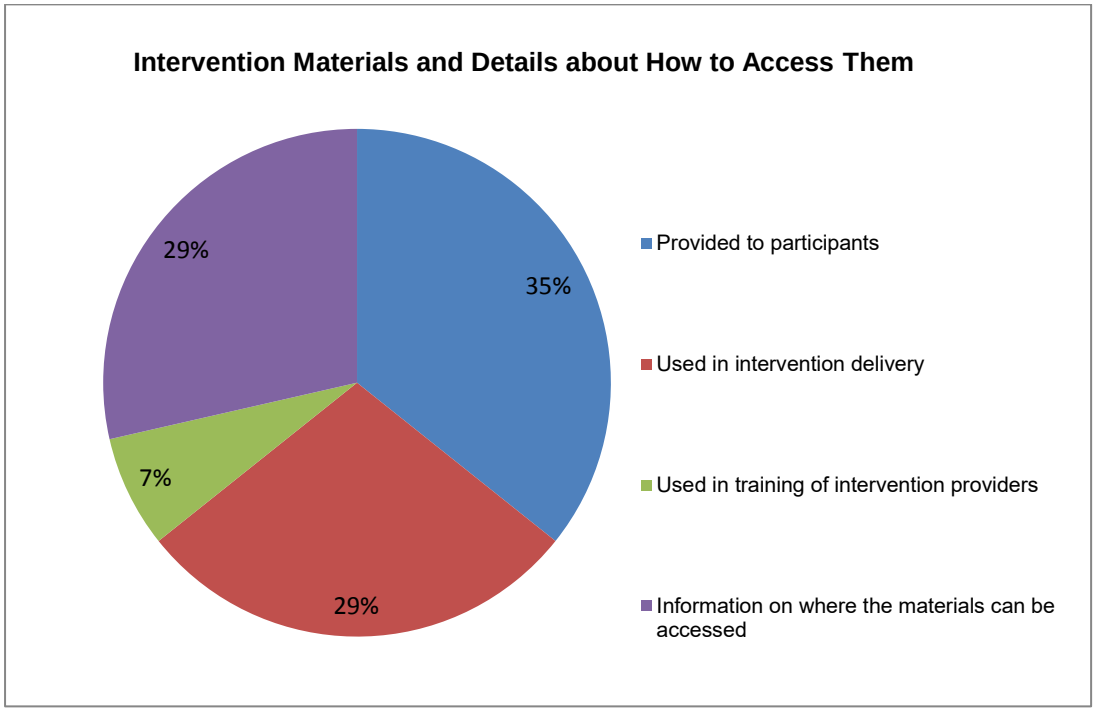

Figure 5: Pie Chart on Intervention Materials and Details about How to Access Them

Table 14: Detailed description of Intervention Materials and Details about How to Access Them

WHAT: PHYSICAL OR INFORMATIONAL MATERIALS USED IN THE INTERVENTION						
RCT	**Provided to participants**	**Used in intervention delivery**	**Used in training of intervention providers**	**Information on where the materials can be accessed**	**TOTAL**	
Hinman et al., 2016	"Participants were provided a pair of appropriately sized shoes on the basis of their random assignment and were asked to wear them as much as possible every day."	"For the intervention, we provided black, commercially available unloading walking shoes (GEL Melbourne OA) with triple density midsoles (stiffer laterally than medially) and mild (5-degree) lateral-wedge insoles attached to the underside of the sock liners."	N	"Appendix Figure, top- Appendix Figure, available at www.annals.org"	3/4	75%
Da Silva et al., 2015	N	N	N	"The education sessions were adapted from a previous paper (reference provided) and consisted of seminars and discussion groups."	1/4	25%
Coleman et al., 2012	"In addition to the weekly sessions, participants are given printed information relevant to the course component discussed each week."	N	N	N	1/4	25%
Hurley et al., 2012	N	"Exercise equipment, materials/photocopying."	N	N	1/4	25%
Kao et al., 2011	N	DVD	N	N	1/4	25%
Ravaued et al., 2009	"Specific documents provided to patients included information on osteoarthritis and a booklet to record weight and physical activities each week."	"Rheumatologists had to implement the US National Institutes of Health evidence based guidelines for management of obesity, a practical patient centred tool for organising information for weight loss counselling. This tool considers particularly the patient's state of readiness to change and intentions regarding implementation."	"To ensure consistency in delivery and content of the intervention, rheumatologists had to use a pre-printed data collection form following algorithms proposed in the National Institutes of Health guidelines to provide this standardised programme, use similar language and explanations at each step of the programme, and provide specific leaflets to patients. Education and advice related to osteoarthritis protect joints (movements to avoid) and the need for physical exercise. Progressive exercise regimen, educated patients about body weight, US National Institutes of Health evidence based guidelines for management of obesity, a practical patient centred tool for organising information for weight loss counselling."	www.nhlbi.nih.gov/guidelines/obesity/prctgd_c.pdf	4/4	100%

Hurley et al., 2007	N	N	N	"The rehabilitation program is outlined in the Appendix (available at the Arthritis Care & Research Web site at http://www.interscience.wiley.com/jpages/0004-3591:1/suppmat/index.html) with a detailed description available at www.kcl.ac.uk/gppc/escape."	1/4	25%
Yip et al., 2007	"a pedometer"	N	N	N	1/4	25%
Nuñez et al., 2006	"All participants were provided with written information on the contents of the session."	N	N	N	1/4	25%
AVERAGE SCORE OF DESCRIPTION					1.56/4	39%

Key: N=No

The aspect '*description of intervention procedures'* only scored 78%. In the RCT form Hurley et al. (2007) it is indicated that the description of the intervention can be found in the appendix or a link should be followed. The link does however not work and the journal is also not available online. Three RCTs (Kao et al., 2011; Hurley et al., 2007; Nuñez et al., 2006) did not report on the element *'any enabling or supporting activates'*.

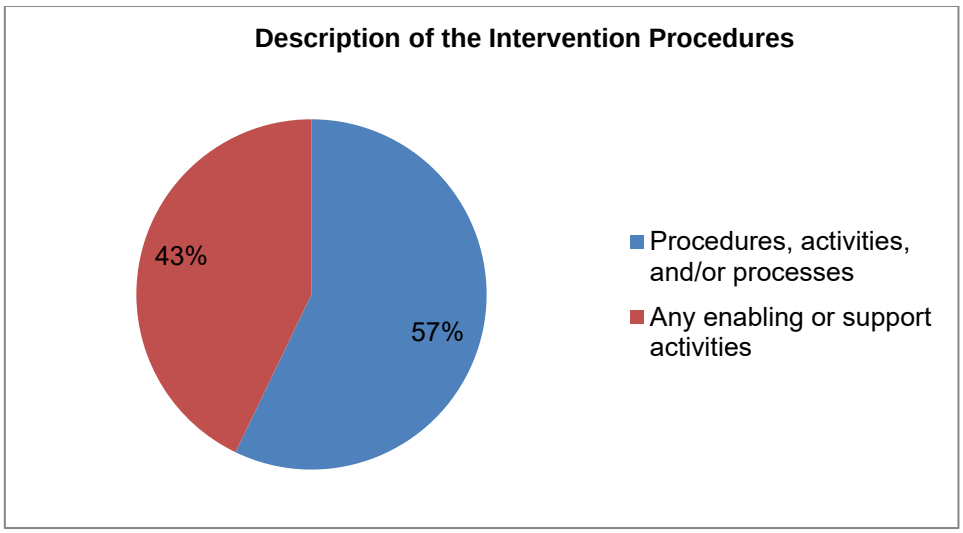

Figure 6: Pie Chart on Description of the Intervention Procedures

Table 15: Detailed description of Description of the Intervention Procedures

WHAT: DESCRIPTION OF THE INTERVENTION PROCEDURES				
RCT	**Procedures, activities, and/or processes**	**Any enabling or support activities**	**TOTAL**	
Hinman et al., 2016	"Participants were provided a pair of appropriately sized shoes on the basis of their random assignment and were asked to wear them as much as possible every day (≥4 hours/day) for 6 months and to avoid changing shoes. Participants were provided the shoes at no cost to themselves and were permitted to keep the shoes regardless of whether they completed the trial."	"Adherence was measured by self-reported wear of allocated shoes (hours per day), which was recorded in a logbook for 7 consecutive days each month; overall self-reported adherence over 6 months using an 11-point numerical rating scale (with the anchors "not worn at all" and "worn completely as instructed"); and a shoe-mounted pedometer (Oregon Scientific PE903) for 7 consecutive days during the fourth week of months 2 and 5 to record the number of daily steps in the trial shoes."	2/2	100%
Da Silva et al., 2015	"This program included educational aspects about knee OA group rehabilitation (15 min) followed by several physical activities (45 min). The education sessions were adapted from Hurley et al. and consisted of seminars and discussion groups, which had the following themes: aims and objectives of the program; identification of personal objectives and recognition of individual functional capabilities; weight control and constituents of a healthy diet, including possible benefits of omega-3; explanation of pain perceptions and biopsychosocial model of pain; no pharmacological procedures of pain management and use of ice and heat when appropriate; and home exercise and home relaxation techniques."	"Physical activities included the following: warm-up for 10 min with a stationary bike and stretching; exercises for the strength of the lower and upper limbs; body mobility, functional, and balance exercises; and relaxation."	2/2	100%

Coleman et al., 2012	The program is implemented using a holistic approach and addresses multiple aspects of care: osteoarthritis (explanation and implications), SM skills (goal-setting, problem-solving, modelling, positive thinking and improving self-efficacy).	medications (types, interactions and current trends), correct use of analgesia (use, therapeutic dosing, types and side effects), pain management strategies (cognitive and pharmacologic), fitness and exercise (strength, flexibility, aerobic and balance), joint protection, nutrition and weight control, fall prevention (balance and proprioception), environmental risks, polypharmacy and coping with negative emotions.	2/2	100%
Hurley et al., 2012	"Participants were invited to attend 12 supervised sessions twice weekly for 6 weeks. For 15–20 minutes of each session, the supervising physiotherapist facilitated a discussion on a specific topic, advising and suggesting simple coping strategies."	"Then, for 35–40 minutes each participant performed a simple individualized exercise regimen to address their disabilities and progressed this as they improved. After completion, participants were discharged with encouragement to perform home exercises and physical activity, especially talking, but did not receive any additional intervention as part of the program."	2/2	100%
Kao et al., 2011	"The intervention included receiving patient education, viewing a DVD, doing exercise, and participating four weekly discussion sessions. It aimed to assist people to maintain a healthy lifestyle, seek support, solve problems and make an action plan."	N	1/2	50%
Ravaued et al., 2009	"Provided education and advice related to osteoarthritis and its treatment. During the second visit (day 15), rheumatologists informed patients about how to protect joints (movements to avoid) and the need for physical exercise. During the third visit (day 30), rheumatologists educated patients about body weight and its influence on osteoarthritis of the knee and proposed a strategy for losing or maintaining weight. They told patients that excess weight would influence their knee pain and the progression of osteoarthritis, that the area of the joint. Contact was approximately $3cm^2$ ($1cm^2$ in cases of meniscectomy), and that the force applied to the joint when walking is equivalent to three times the person's weight. In the case of osteoarthritis of one knee, with excess weight the risk of developing osteoarthritis of the other knee at two years is 54%; otherwise, the risk is 14%. The risk of worsening bilateral osteoarthritis of the knee is threefold that without excess weight."	"They proposed a progressive exercise regimen consisting of three sessions of 30 minutes a week progressively increased to three sessions of 60 minutes a week of rapid walking or cycling depending on the patient's preference. In addition, specific documents provided to patients included information on osteoarthritis and a booklet to record weight and physical activities each week."	2/2	100%
Hurley et al., 2007	? Link not working, journal unavailable	? Link not working, journal unavailable	0	0
Yip et al., 2007	"The programme focused on teaching participants how to cope with and manage common knee OA consequences, such as arthritis pain, fatigue, daily activity limitations and stress. It was designed to give participants skills they could use to optimize their ability to manage their condition."	"An action plan using three types of exercise was promoted and reinforced weekly during the programme. These were stretching exercises, walking, and Tai Chi types of movement – fluid, gentle, relaxed and slow in tempo movement – aimed at enhancing exercise for the affected joints. In addition, routine conventional treatment (treatment prescribed by orthopaedic doctor or outpatient clinic) was continued."	2/2	100%
Nuñez et al., 2006	"All participants were provided with written information on the contents of the sessions These contents were cantered on the consequences of the disease on daily life and included principles of economy/energy conservation and joint protection; valuation and control of pain (rest and positioning, ice and heat, necessary length of application) and treatments recommended for the management of knee OA; demonstration and use of assistive devices and tables of physical exercises with no burden on the lower limbs, with specific knee exercises to maintain and improve the strength of muscles acting around the knee, the range of motion at the knee joint, and locomotors function; and general exercises to mobilize the joints and strengthen the musculature of the rest of the body. Patients were instructed to increase the number of repetitions up to a maximum of 30 times, twice a day, for the knee exercises, and 10 times, once a day, for the general exercises, according to individual tolerance to pain. The exercises were taught in the group sessions. Patients were instructed to practice the exercises at home in the week previous to the second group session, in which all patients carried out the complete table of exercises, supervised by the educator. Follow-ups were performed in the individual visits."	N	1/2	50%
AVERAGE SCORE OF DESCRIPTION			1.56/2	78%

Key: N=No

All of the RCTs (9/9) reported on the aspect *'details of intervention providers'* It varied between researchers, health care professionals such as students of physiotherapy or physiotherapists, nurses, occupational therapists, rheumatologists, health educators or community leaders. The elements are only 36% described in the RCTs with the *'expertise'*, *'background'* and *'specific training given'* to the intervention providers rarely mentioned. The *'expertise'* are mentioned in four of the RCTs (Coleman et al., 2012; Hurley et al., 2012; Kao et al., 2011; Yip et al., 2007). *'Specific raining given'* to the intervention providers are described in only one RCT (Da Silva et al., 2015). No description on the element '*background*' is given.

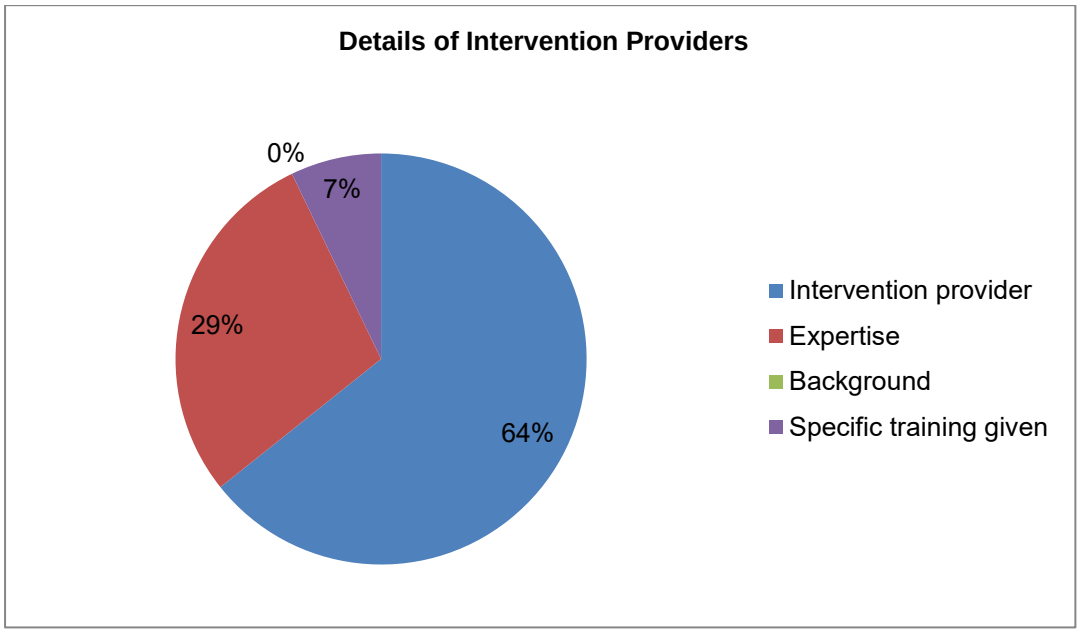

Figure 7: Pie Chart on Details of Intervention Providers

Table 16: Detailed description of Details of Intervention Providers

WHO: DETAILS OF INTERVENTION PROVIDERS						
RCT	**Intervention provider**	**Expertise**	**Back-ground**	**Specific training given**	**TOTAL**	
Hinman et al., 2016	"A researcher."	N	N	N	1/4	25%
Da Silva et al., 2015	"Four students of physiotherapy duly trained."	N	N	Y	1/4	25%
Coleman et al., 2012	"Health care professionals, including nurses, physiotherapists and occupational therapists, who deliver this program."	"Must have a minimum level of musculoskeletal education to ensure that they have the necessary knowledge and skills to present information about OA of the knee and respond accurately to complex questions."	N	N	2/4	50%
Hurley et al., 2012	"Physiotherapist"	"13 years of postgraduate clinical experience."	N	N	2/4	50%
Kao et al., 2011	"Led by a physical therapist."	"Trained in leading small groups and in self-management."	N	N	2/4	50%
Ravaued et al., 2009	"Rheumatologists"	N	N	N	1/4	25%
Hurley et al., 2007	"Experienced physiotherapist"	N	N	N	1/4	25%
Yip et al., 2007	"Led by registered nurses."	"Trained in leading small groups and in self-management."	N	N	2/4	50%
Nuñez et al., 2006	"Trained health educator."	N	N	N	1/4	25%
AVERAGE SCORE OF DESCRIPTION					1.44/ 4	36%

Key: N=No

The majority of interventions were delivered face-to-face or in a group setting. Groups varied between 6-15 participants. Patients were also seen individually in four RCTs (Hurley et al., 2012; Ravaued et al., 2009; Hurley et al., 2007; Nuñez et al., 2006).

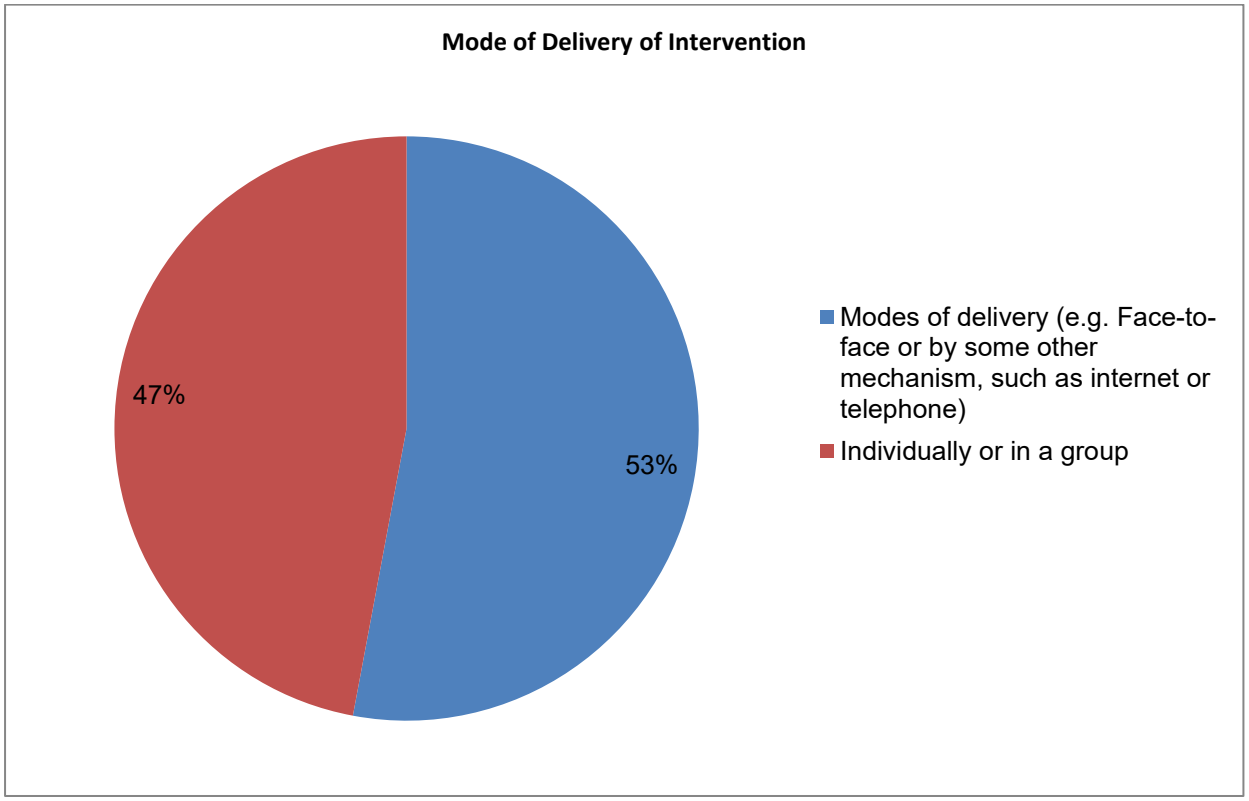

Figure 8: Pie Chart on Mode of Delivery of Intervention

Table 17: Detailed description of Mode of Delivery of Intervention

HOW : MODE OF DELIVERY OF INTERVENTION				
RCT	**Modes of delivery (e.g. Face-to-face or by some other mechanism, such as internet or telephone)**	**Individually or in a group**	**TOTAL**	
Hinman et al., 2016	"For the intervention, we provided."	N	1/2	50%
Da Silva et al., 2015	"The education sessions consisted of seminars and discussion groups."	Groups	2/2	100%
Coleman et al., 2012	"Face-face"	"Group setting optimal 12 participants."	2/2	100%
Hurley et al., 2012	"Face-face"	"Self-delivered to individual participants or small groups of 8 participants."	2/2	100%
Kao et al., 2011	"Face-face"	"Small group approach 15 - 10 participants."	2/2	100%
Ravaued et al., 2009	"Face-face"	"Visits, individual consultation."	2/2	100%
Hurley et al., 2007	"Face-face"	"Individually or groups rehabilitation."	2/2	100%
Yip et al., 2007	"Face-face"	"The classes were conducted using a small group approach with 10–15 participants."	2/2	100%
Nuñez et al., 2006	"Face-face"	"Two individual visits, two group sessions for a maximum of 10-12 patients. The exercises were taught in the group sessions, follow-ups were performed in the individual visits."	2/2	100%
AVERAGE SCORE OF DESCRIPTION			1.89/2	94.44%

Key: N=No

Another large aspect that is poorly reported on is the *'description of location of intervention delivery and key infrastructure'.* The description is only 29.63% complete with no RCT reporting on all the elements. The most RCTs (8/9) report on the city or town where the intervention is provided. The missing gaps are the elements *'necessary infrastructure'* and the *'relevant features'* of the locations.

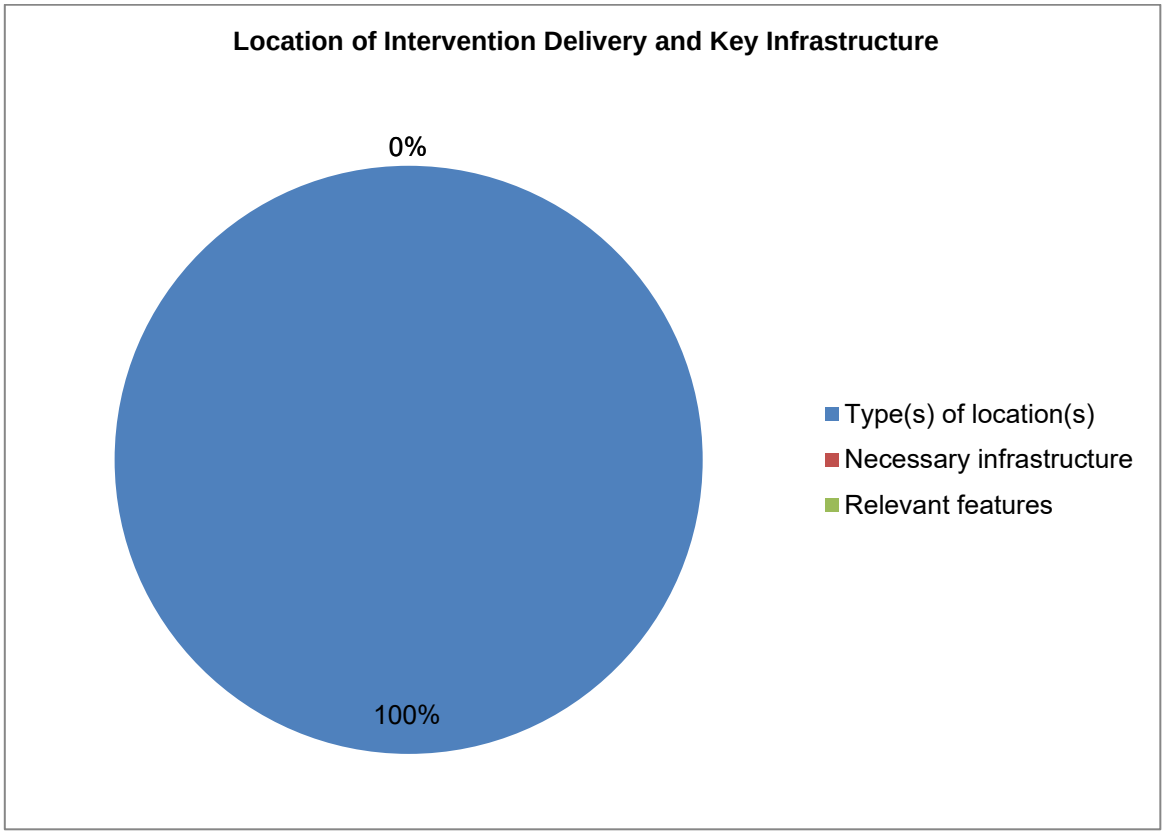

Figure 9: Pie Chart on Location of Intervention Delivery and Key Infrastructure

Table 18: Detailed description of Location of Intervention Delivery and Key Infrastructure

WHERE: LOCATION OF INTERVENTION DELIVERY AND KEY INFRASTRUCTURE					
RCT	**Type(s) of location(s)**	**Necessary infrastructure**	**Relevant features**	**TOTAL**	
Hinman et al., 2016	Melbourne, Australia	N	N	1/3	33.33%
Da Silva et al., 2015	N	N	N	0/3	0%
Coleman et al., 2012	Community venue	N	N	1/3	33.33%
Hurley et al., 2012	Southeast London	N	N	1/3	33.33%
Kao et al., 2011	Districts in Taipei City	N	N	1/3	33.33%
Ravaued et al., 2009	Primary care in France	N	N	1/3	33.33%
Hurley et al., 2007	"All assessments were conducted in the Rehabilitation Research Unit, Dulwich Community Hospital and all rehabilitation sessions performed in the Physiotherapy Out-patient Department"	N	N	1/3	33.33%
Yip et al., 2007	"Orthopaedic Department of a local hospital, the general outpatient clinic of a local hospital and the Wellness Clinic Hong Kong China"	N	N	1/3	33.33%
Nuñez et al., 2006	'Urban tertiary care centre, the Hospital Clinic, Barcelona (Spain)"	N	N	1/3	33.33%
AVERAGE SCORE OF DESCRIPTION				0.89/3	29.63%

Key: N=No

The aspect *'details about the number, duration, intensity, and dose of intervention sessions'* is 24.45% incomplete. All the RCTs reported on the element *'over what period of time'. However, the* other elements *'theirs schedule* (4/9), *'number of sessions'* (7/9) and *'duration, intensity or dose'* (5/9) lacked the most description.

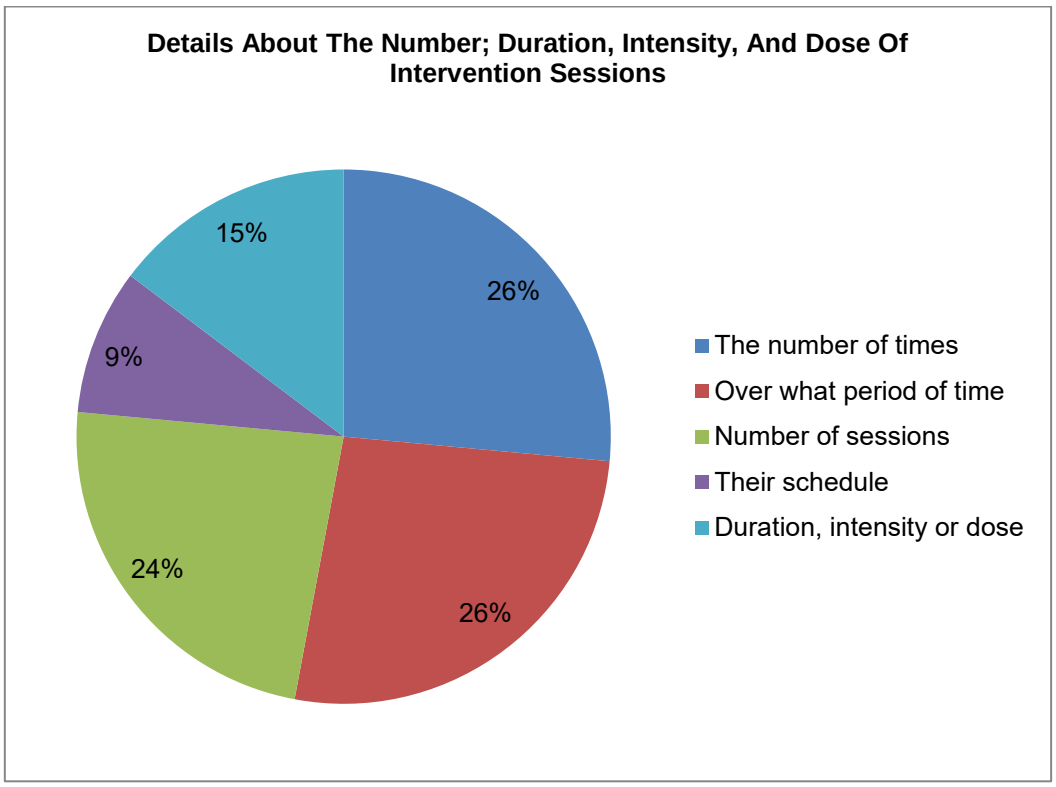

Figure 10: Pie Chart on Details about the Number, Duration, Intensity, and Dose of Intervention Sessions

Table 19: Detailed description of Details about the Number, Duration, Intensity, And Dose of Intervention Sessions

WHEN AND HOW MUCH: DETAILS ABOUT THE NUMBER, DURATION, INTENSITY, AND DOSE OF INTERVENTION SESSIONS							
RCT	**The number of times**	**Over what period of time**	**Number of sessions**	**Their schedule**	**Duration, intensity or dose**	**TOTAL**	
Hinman et al., 2016	"Participants were asked to wear them as and to avoid changing shoes."	"For 6 months"	"As much as possible every day (≥4 hours/day)"	N	N	2/5	66.67%
Da Silva et al., 2015	"Twice a week for 8 weeks = 16"	"8 weeks"	"60 min sessions performed twice a week"	"The intervention group participated in a group rehabilitation program that consisted of 60 min sessions performed twice a week for a period of 8 week. This program included educational aspects about knee OA group rehabilitation (15 min) followed by several physical activities (45 min)."	"Educational aspects about knee OA group rehabilitation (15 min) followed by several physical activities (45 min)"	5/5	100%
Coleman et al., 2012	"Six weekly sessions for 6 weeks = 36"	"6 weeks"	N	N	"2.5 hours each"	3/5	60%
Hurley et al., 2012	"12 supervised sessions twice weekly for 6 weeks."	"6 weeks"	"12 supervised sessions"	"12 supervised sessions twice weekly for 6 weeks. For 15–20 minutes of each session, the supervising physiotherapist facilitated a discussion on a specific topic, advising and suggesting simple coping strategies. Then, for 35–40 minutes each participant performed a simple individualized exercise regimen to address their disabilities and progressed this as they improved."	"15–20 minutes of each session discussion 5–40 minutes exercise regimen"	5/5	100%
Kao et al., 2011	"Four classes held once a week for 4 weeks = 16"	"4 weeks"	"Four classes held once a week for 4 weeks = 16"	N	N	3/5	60%
Ravaued et al., 2009	"Day 0, Day 15 and day 30 =3"	"1 month"	3	"Day 0, Day 15 and day 30"	N	4/5	80%
Hurley et al., 2007	"12 supervised sessions"	"6 weeks"	"Twice weekly"	N	N	3/5	60%
Yip et al., 2007	"Six classes once a week 6 months = 36"	"for 6 months"	"Once a week"	N	"2-hour classes"	4/5	80%
Nuñez et al., 2006	"3-month program consisted of two individual visits lasting about 30 min at first week and at 3 months, and two group sessions of about 90 min in weeks 3 and 4 = sessions"	3 months	"First week 3 months in weeks 3 and 4"	"3-month program consisted of two individual visits lasting about 30 min at first week and at 3 months, and two group sessions of about 90 min in weeks 3 and 4."	"30 min and about 90 min"	5/5	100%
AVERAGE SCORE OF DESCRIPTION						3.78/5	75.56%

Three RCTs tailored their interventions (Hurley et al., 2012, Ravaued et al., 2009, Hurley et al., 2007) but only one (Ravaued et al., 2009) described the element *'how'* and two (Hurley et al., 2012, Ravaued et al., 2009) described the element *'why'*. As seen in table 29, the tailoring was done for additional exercise programs and individual goal setting. The aspect description is 86.67% incomplete

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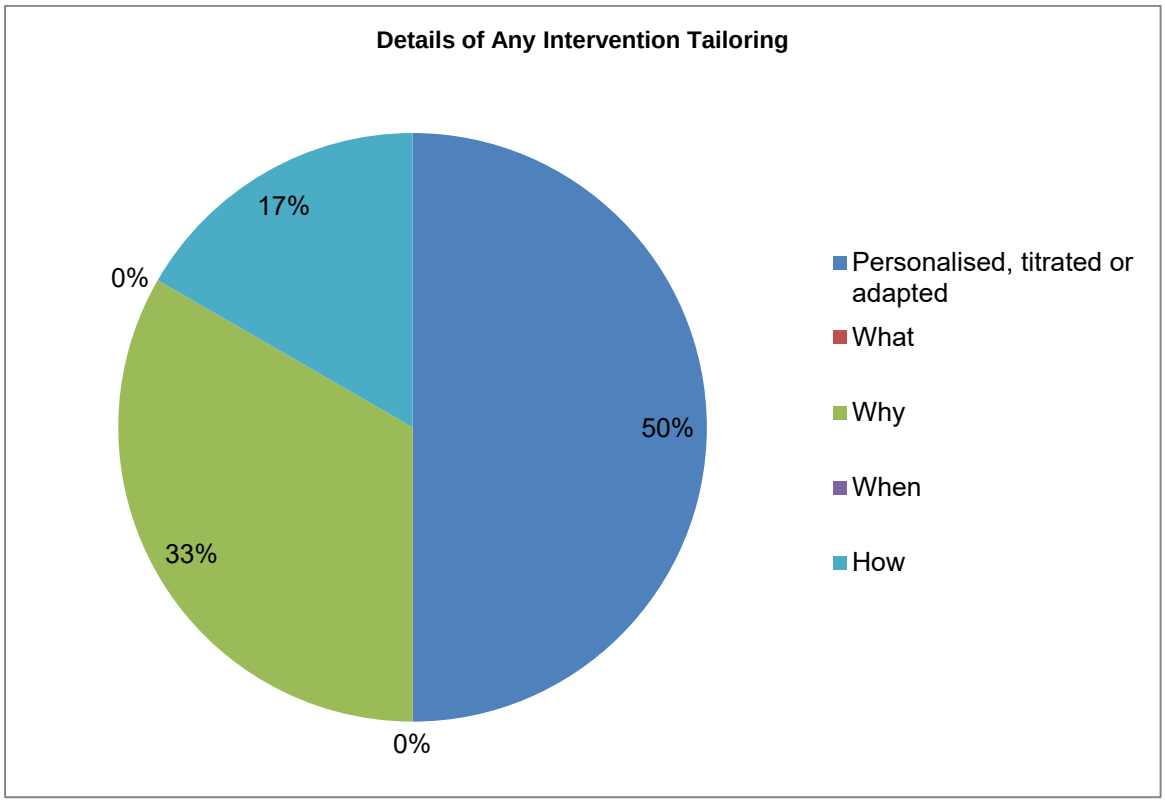

Figure 11: Pie Chart on Details of Any Intervention Tailoring

Table 20: Detailed description of Details of Any Intervention Tailoring

TAILORING: DETAILS OF ANY INTERVENTION TAILORING							
RCT	**Personalised, titrated or adapted**	**What**	**Why**	**When**	**How**	**TOTAL**	
Hinman et al., 2016	N	N	N	N	N	0/5	0%
Da Silva et al., 2015	N	N	N	N	N	0/5	0%
Coleman et al., 2012	N	N	N	N	N	0/5	0%
Hurley et al., 2012	"Individualized exercise regimen"	N	"To address their disabilities and progressed this as they improved."	N	N	2/5	40%
Kao et al., 2011	N	N	N	N	N	0/5	0%
Ravaued et al., 2009	"Tailored counselling of patients to increase the odds of achieving modification of behaviour."	N	"The exercise programme took into account patients' preferences, and the strategy for losing or maintaining weight varied"	N	"According to patients' readiness to change"	3/5	60%
Hurley et al., 2007	"Individualized, progressive exercise regimen"	N	N	N	N	1/5	20%
Yip et al., 2007	N	N	N	N	N	0/5	0%
Nuñez et al., 2006	N	N	N	N	N	0/5	0%
AVERAGE SCORE OF DESCRIPTION						0.67/5	13.33%

Key: Y=Yes; N=No

No intervention modifications were made throughout any study

Table 21: Any Intervention Modifications throughout the Study

INTERVENTION MODIFICATIONS THROUGHOUT THE STUDY				
RCT	**Modified**	**Describe the changes**	**TOTAL**	
Hinman et al., 2016	N	N	0/2	0%
Da Silva et al., 2015	N	N	0/2	0%
Coleman et al., 2012	N	N	0/2	0%
Hurley et al., 2012	N	N	0/2	0%
Kao et al., 2011	N	N	0/2	0%
Ravaued et al., 2009	N	N	0/2	0%
Hurley et al., 2007	N	N	0/2	0%
Yip et al., 2007	N	N	0/2	0%
Nuñez et al., 2006	N	N	0/2	0%
AVERAGE SCORE OF DESCRIPTION			0/2	0%

Key: Y=Yes; N=No

Although adherence was assessed because dropout rates were available in 8/9 RCTs (as seen in Table 22), only one RCT (Hinman et al., 2016) reported on the element *'how'* and *'whom'*. Coleman et al. (2012) reported on how adherence can be maintained. Table 22 indicates the average score is 1.3/4. Overall the adherence element is only 33.25% described in the 9 RCTs.

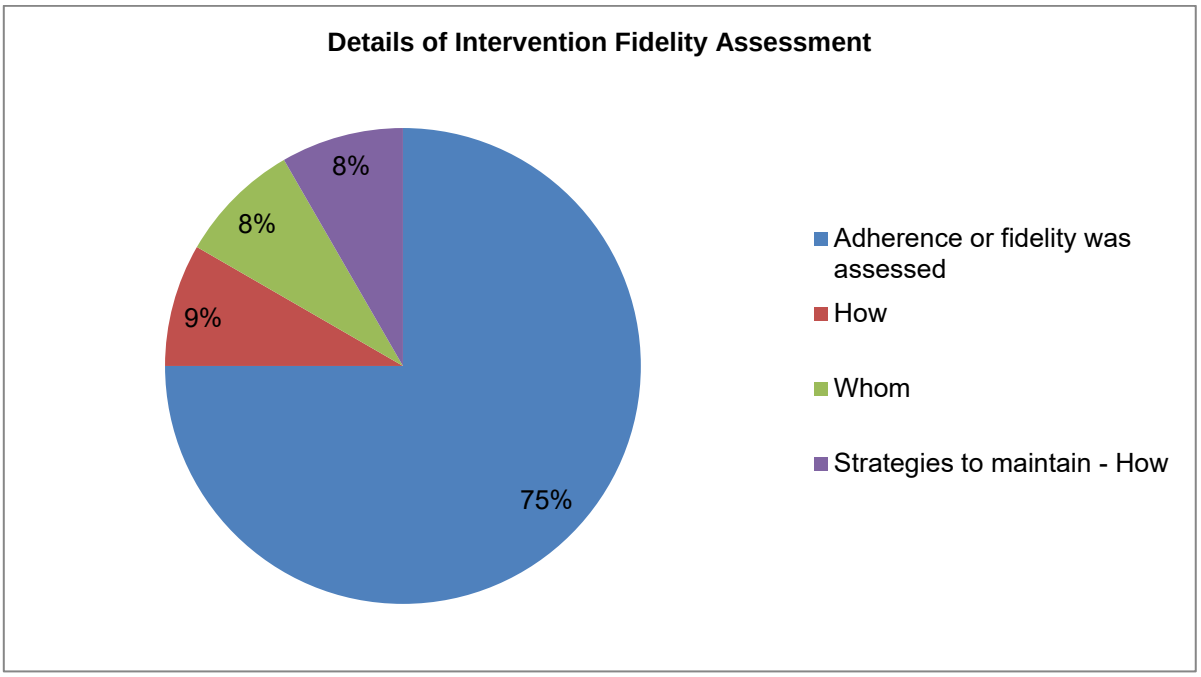

Figure 12: Pie Chart on Details of Intervention Fidelity Assessment

Table 22: Detailed description of Details of Intervention Fidelity Assessment

HOW WELL: DETAILS OF INTERVENTION FIDELITY ASSESSMENT						
RCT	**Adherence or fidelity was assessed**	**How**	**Whom**	**Strategies to maintain - How**	**TOTAL**	
Hinman et al., 2016	Y	"Adherence was measured by self-reported wear of allocated shoes (hours per day), which was recorded in a logbook for 7 consecutive days each month; overall self-reported adherence over 6 months using an 11-point numerical rating scale (with the anchors "not worn at all" and "worn completely as instructed"); and a shoe-mounted pedometer (Oregon Scientific PE903) for 7 consecutive days during the fourth week of months 2 and 5 to record the number of daily steps in the trial shoes."	"Self-reported"	N	3/4	75%
Da Silva et al., 2015	Y	N	N	N	1/4	25%
Coleman et al., 2012	"The program aims to maximize the benefits of physical activity and promote long-term adherence to an exercise regimen"	N	N	"Structured exercise participation that is linked to weekly SMART' goals (Specific, Measurable, Attainable, Realistic, Time-bound)"	2/4	50%
Hurley et al., 2012	Y	N	N	N	1/4	25%
Kao et al., 2011	Y	N	N	N	1/4	25%
Ravaued et al., 2009	Y	N	N	N	1/4	25%
Hurley et al., 2007	Y	N	N	N	1/4	25%
Yip et al., 2007	Y	N	N	N	1/4	25%
Nuñez et al., 2006	Y	N	N	N	1/4	25%
AVERAGE SCORE OF DESCRIPTION					1.33/4	33.25%

Key: Y=Yes; N=No

Table 23: Detailed description of Intervention Fidelity Level Achieved

HOW WELL: EXTENT TO WHICH THE INTERVENTION WAS DELIVERED AS PLANNED				
RCT	**YES**	**NO**	**TOTAL**	
Hinman et al., 2016	"Retention was excellent at 6 months; only 4 (2%) participants did not complete primary outcome measure."		1	100%
Da Silva et al., 2015	"During the 8 week trial, four intervention participants declined to take part in this work due to absences (n = 1) or personal reasons (n = 3). In parallel, seven controlled participants dropped out due to health problems (n = 2) or personal reasons (n = 5)."		1	100%
Coleman et al., 2012	"The mean (median) attendance in the OAK group was 5.77 (6) sessions. The reasons cited for withdrawal were overseas relocation; work, family and time commitments; and not having been randomised to the OA knee group."		1	100%
Hurley et al., 2012	"Of the 418 participants recruited, 375 (90%) were assessed on at least 1 follow-up occasion. At 30 months, data were available from 283 participants (68%)."		1	100%
Kao et al., 2011	"Among these participants, 134 people were in the IG and 125 people were in the controlled group. In the intervention group, eight people were dropouts. In the end, 126 (70%) completed the intervention and 1 week post-intervention questionnaires."		1	100%
Ravaued et al., 2009	"More than 95% of patients in the intervention group and 96% of patients in the control group attended all three consultations."		1	100%
Hurley et al., 2007	"Of the participants who attended 6-month follow-up, 105 (85%) of 120 individual-rehab participants and 59 (55%) of 107 Group-rehab participants attended 10 of the 12 sessions."		1	100%
Yip et al., 2007	"For the 182 participants enrolled in the study, 1-week post intervention was completed with 149 and 16 week post intervention with 120."		1	100%
Nuñez et al., 2006	"Twenty patients were lost to the study, eight in the intervention group (death in two patients, severe pathology in two, loss of contact in one, and drop out in three patients) and 12 in the control group (death in two patients, severe pathology in one, loss of contact in two, transfer out to other autonomous communities in two, and drop out in five patients)."		1	100%
AVERAGE SCORE OF DESCRIPTION			9/9	100%

Key: Y=Yes; N=No

4.6 Description of Constrains of Replication in Clinical Practice

The local contextual issues which could constrain immediate uptake of recommendations as reported in the included RCTs are outlined in Table 24.

Table 24: The Constrains of Replication in Clinical Practice

	Physiotherapist issues	Patient issues
Hinman et al., 2016	Handing out shoes as an intervention in areas with poor infrastructure will not plausible.	Patients can easily commit to wearing shoes.
Da Silva et al., 2015	Education sessions consisting of seminars and discussion groups with pamphlets can be delivered by a physiotherapist, however it will be challenging to continue with the program for 60 min, twice a week for 8 weeks, due to physiotherapist not being able to provide services so regularly as a result of the shortage of healthcare professionals.	It will be challenging for patients to access the PHC setting twice a week due to financial implications and transport barriers such as distances, uneven terrains and the lack of a reliable transportation.
Coleman et al., 2012	The educational part of the program is detailed and is recommended to be delivered by healthcare professionals rather than by lay leaders. This will increase the workload of the physiotherapist. The group sessions however makes it more easily to carry out. Sessions has to be done for 2.5h for 6 weeks. The physiotherapist has to have resources available to print information to patients.	Printed information can be challenging if not in the patients home language and patients might not be literate or have low educational levels. Adherence for 6 weeks can be challenging.
Hurley et al., 2012	Discussion was only facilitated by the physiotherapist and will be easily carried out. However 12 supervised sessions twice a week for 6 weeks by the same physiotherapist (to ensure consistency) will be a workforce together with a financial barrier.	Financial implications will make the intervention difficult to adopt. Patients will often struggle with transport cost to access the clinic and also have to navigate the terrain.
Kao et al., 2011	The physiotherapist has to give 80 min classes for four weeks. The education part consists of Power Point presentations with DVDs. This might not always be possible to carry out due to electricity resources or a device used for viewing.	The presented information on the PowerPoint and DVDs has to be in the patient's own language, education level, and specific to the local culture and in tune with the ethnic group.
Ravaued et al., 2009	The intervention is provided by rheumatologist and the physiotherapist might possibly need training to provide the intervention. Three individual consolations has to be done in a month, leaflets and booklets has to be provide and the physiotherapist also have to make use of the NICE tools. The physiotherapist will therefore have to have resources available of internet to access the NICE guidelines, printing of leaflets and booklets has to be done and the physiotherapist will have to visit a clinic 3 times a month.	The intervention includes the recommendation of walking or cycling – a patient who does not have the resources available of a bicycle is given the option to walk.
Hurley et al., 2007	Some appendix not available online. 12 supervised sessions over 6 weeks has to be done. Workforce is often not available and there should be made use of an additional healthcare presenter such as a nurse.	Financial implications will be a challenge. Accessing the clinic twice a week can lead to financial implications of transport. A stigma can also develop if a patient has to visit the clinic so often. The discussions will have to be presented in such a way that everyone understands, no matter their educational level.
Yip et al., 2007	Again the sessions are too much and too often – 6 2 hour classes held once a week for. The physiotherapist will often not be able to visit a clinic that often and other available healthcare workers will have to be trained. The materials used are pedometers. An alternative will have to be considered in areas with limited resources.	Patients will be financially, socially and physically burdened when having to access the clinic on such a regular bases. This can also increase the chances of patients dropping out of the program.
Nuñez et al., 2006	The intervention is done over a 3 month period. The physiotherapist workload can be decreased by the means of an assistant. The therapist will have to have resources available to provide written information.	The written information has to be translatable to patients preferred language and appropriate to the patients' culture. Patients will have to trust another individual to accompany them to the sessions.

CHAPTER 5

DISCUSSION

This is the first study, to your knowledge, that examines the level of detail provided in recent high-quality clinical practice guidelines (CPGs) and randomised controlled clinical trials (RCTs) regarding physiotherapy-based self-help and education interventions for patients with osteoarthritis (OA) of the knee. Through this approach, we investigated how much detail was lacking from descriptions of interventions in published studies and CPGs, and how this lack of detail may hinder reproducibility in clinical practice, particularly for the South African Primary Health Care (PHC) settings. Ensuring that a study's interventions are described adequately so that it can be reproduced in clinical practice is a fundamental part of adding value to research, and in ensuring evidence-based practice occurs (Duet et al., 2013).

The primary purpose of this study was to ascertain logistics of the methods required to extract data for the description of the intervention from CPGs and RCTs to inform replication in clinical practice. The results of this study will inform a larger study which aims to further investigate ways in which the CPG recommended interventions could be delineated into a more clinician-friendly format, for example a mobile application or a flipchart, which would make the implementation and comprehension by any clinician in any setting, especially at PHC level, easier and user friendly. Through the process of ascertaining the exact methods which would inform the larger project we discovered a number of logistical issues (such as CPGs being incomplete, websites not open or available, a large number of pathologies needing to be addressed). This study was therefore valuable and important to conduct as an initial step to accurately inform the larger project. As a starting point, knee OA was chosen due to it being a very prevalent condition in the South African PHC settings (Allen et al., 2010).

Initially, five CPGs were considered from across the different data clearing houses, but after excluding three only two CPGs (National Clinical Guideline Centre, 2014; McAlindon et al., 2014) could be included. Within the included CPGs, the self-help and education sections were scrutinised to identify the relevant RCTs for inclusion. Using the included CPGs reference list, the list of relevant RCTs used in the CPGs were extracted onto a dataset. Additionally, the dataset was updated with more recent RCTs after a literature search was conducted in electronic databases.

The RCTs used in this review ranged from being published between 2006 and 2016. The nine RCTs were conducted in both developed countries, including Australia, England, France and Spain as well as in developing countries including Brazil, Taiwan and China. Four RCTs (Hinman et al., 2016; Coleman et al., 2012; Ravaued et al., 2009; Hurley et al., 2007) specifically stated that their intervention was completed on community or primary care level. South Africa is still a developing country and interventions that are performed on community level will therefore be more appropriate. The population of the RCTs was similar due to the similar inclusion and exclusion criteria for the participants of the individual RCTs. Participants were mostly older than 50 years, had to be able to rate their pain on a standardised pain scale, had radiographic changes, had morning stiffness lasting less than 30 min or scored low on a standardised functional outcome measurement. Three RCTs (Da Silva et al., 2015; Ravaued et al., 2009; Yip et al., 2007) specifically made use of the American College of Rheumatology Criteria for their inclusion of participants. The similarity of the population of the RCTs does not only simplify the implementation of the interventions, but enhance the ease of the reproducibility of the interventions in clinical practice.

To be included, the RCTs had to score a minimum of 5/10 on the PEDro score as this indicates acceptable external and internal validity (Verhagen et al., 1998). However, the quality of the RCTs varied. Of the RCTs critically appraised in this review, the following criteria were frequently not met: concealed allocation, blinding of subjects and blinding of administrating therapists. Concealed allocation affects the group that the participant is allocated to. When allocation to the different groups are

not concealed, systematic bias can occur which will affect the methods through the implementation of the intervention as well as the manner in which the results will be interpreted (Tooth et al., 2005). If group allocation is not concealed, subjects will be aware in which group they are participating in. Blinding of subjects affects the patients' perception and beliefs on the treatment while blinding of administrating therapists affects the administrating therapists' treatment attitude (Tooth et al., 2005). Although typically you can't blind the therapist and subject in therapeutic trials, the nature of the interventions in the include RCTs (self-help and education) makes it possible that blinding to an extent could have been conducted, especially because self-help and education as interventions have a subjective component. The administrating therapist can unconsciously convey a message to the patients reflecting their own opinion of the intervention (Tooth et al., 2005). If the subjects are not blinded, a mental component gets involved (Tooth et al., 2005). Furthermore non-blinding can also affect the compliance to the interventions (Tooth et al., 2005). All of the factors affect the internal validity and can therefore have an effect on the reproducibility of the studies in clinical practice.

To assess the level of detail described for interventions in the included studies, the Template for Intervention Description and Replication (TIDieR) data extraction tool was used (Yamato et al., 2015; Hoffmann et al., 2014). Each aspect was examined, as outlined by the TIDieR, and the individual elements of each aspect were scored. A general score for each aspect was also given. 'Yes' scores were assigned where more than half of the elements for each TIDieR aspect was clearly described, and 'No' scores were assigned where there was no information provided on the element or less than half of the elements were described for each TIDieR aspect. 'Part' marks were assigned where the RCT provided some but not all details on each element.

A strength of this study is that the TIDieR is an externally produced and tested criteria that was applied to evaluate the descriptions of the interventions and completed by two separate investigator. A part of the method was that the TIDieR instrument itself required braking down each aspect, by scoring it additionally, to

clarify all the items. Therefore, each component had to be given an individual score. The type of data collected is however dichotomous and a limitation to the study is that the investigators can have different grades of interpretation. This can lead to either the investigators being too lenient or too harsh. Additionally, the TIDieR needed further elements to enable interpretation of the findings into PHC settings in South Africa. The additional checklist, exploring the constrains of replication in clinical practice, was created to contextualise the findings to a South African PHC setting and to summarize any gaps in the ways that RCTs describe self-help and education for knee OA and how these gaps may constrain replication in clinical practices. It was investigated how interventions could be implemented without change in a clinical setting.

Certain aspects of the TIDieR were well described, such as *'name of the intervention'*, *'intervention rationale for essential elements'*, *'description of the intervention procedures'*, '*mode of delivery of intervention'* and *'details about the number; duration, intensity, and dose of intervention sessions'*. Other aspects, however, scored less well such as *'intervention materials and details about how to access them'*, *'details of intervention providers'*, *'location of intervention delivery and key infrastructure'*, *'details of any intervention tailoring'*, *'any intervention modifications throughout the study'*, and *'details of intervention fidelity assessment, monitoring, and level achieved'*.

Seven of the nine included studies reported on the aspect *'name or phrase for their intervention'* (see Table 13). A full description was provided for the aspect *'rationale, theory, or goal of the elements'* essential to the intervention which consisted of three elements (*'rationale', 'theory', 'goal'*). However it can be seen that only one RCT (Da Silva et al., 2015) did not report on the *'goal'* element. Clinicians typically search for or base their choice of CPG selection on a specific condition. The name of the intervention is usually used to describe the intervention, which will influence the clinician's choice. It is therefore important that the name/phrase of the intervention in all studies is provided.

It is well-known that information in booklets and hand-outs for patients to assist them in self-managing is often an area that lacks detail in published studies or reference as to where the information can be accessed is typically missing (Duet et al., 2013). Seven of the nine (77.78%) included RCTs did not provide enough information with regards to the aspect *'intervention materials and details about how to access them'*. Only one RCT gave a complete description of all four the elements of this aspect (Ravaued et al., 2009). *'Physical or informational materials used in the intervention delivery'* were mentioned in four (Hinman et al., 2016; Kao et al., 2011; Hurley et al., 2012; Ravaued et al., 2009) out of the 9 included RCTs. Examples of the materials included shoes, DVDs and written information. However, as seen in Table 17, although the materials are mentioned, no description or details are given about the materials. Regrettably the element *'information on where to access the materials'*, was also only half complete and only provided in 4 out of the 9 RCTs (Hinman et al., 2016; Da Silva et al., 2015; Ravaued et al., 2009; Hurley et al., 2007). The information provided is therefore typically not enough to enable a clinician to reproduce the promotional and interventional materials or access the information or materials for use in clinical practice. And when providing details on physical and information materials, the local context is very important to consider (Duet et al., 2013). Language and level of education will impact not only the format of the materials provided, but also differ from target group to target group (Duet et al., 2013). Certain resources are scares and limited in rural areas, such as electricity, electronic equipment (computers, cell phones, laptops, tablets) and internet. When considering the availability, a large obstacle to overcome will be to access the guidelines or the intervention material from the RCTs.

Apart from the *'information in the materials and details about how to access them'* aspect, the most detail lacked for the element *'materials used in training of intervention providers'* with only one RCT (Ravaued et al., 2009) providing details. When considering a context where there are workforce shortages, it is a possible that other healthcare providers (such as nurses, home based carers or occupational therapists) or community members will have to assist in the intervention delivery and

will therefore have to be adequately trained. It is important that the trainees obtain the necessary background knowledge so that the same goals, as was intended by the original study, will be achieved (Visagiel & Schneider, 2014).The total aspect *'details of the intervention providers'* were 44.44% adequately described by the RCTs. Although the intervention providers were mention (ranging from physiotherapists, students, nurse, rheumatologists or trained healthcare providers), the specific training given to the intervention providers was only described in one RCT (Da Silva et al., 2015) and no background were given about the intervention providers in any RCT. The element *'expertise'* of the aspect *'details of the intervention providers'* was mentioned in four RCTs (Coleman et al., 2012; Kao et al., 2011; Hurley et al., 2012; Yip et al., 2007). Implementation of an intervention is influenced by predisposition together with the intervention providers or clinicians' attitudes and adequate training of the intervention provider is therefore of utmost importance (Sherry, 2014). With the information lacking in the RCTs, training will be challenging and will either be done very poorly or inadequate. RCTs form the baseline of CPGs (Douet et al., 2013) and therefore contextualising the CPGs intervention will be puzzling because every clinician interprets information differently.

The TIDieR aspect *'mode of delivery of the intervention'* was well (100%) described by all nine studies. The majority of the studies (n=8) delivered their intervention face to face and made use of groups ranging from 8-15 participants. Individual sessions were also done in four RCTs (Hurley et al., 2012; Ravaued et al., 2009; Hurley et al., 2007; Nuñez et al., 2006). Considering particularly the in rural and remote regions where there are workforce and resource shortages, individual sessions will not always be possible in a PHC context (Visagiel & Schneider, 2014). The format of the sessions will be dependent on the resources available (Visagiel & Schneider, 2014) and group sessions in rural areas with workforce deficiency will mostly be ideal. Other options such as home visits or follow up telephone calls can also be considered when the patients face financial or physical challenges in reaching the clinic to access best possible health care (Lorenzo et al., 2015).

The aspect *'description of the intervention procedure',* together with the aspect *'details about the number, duration, intensity and dose of intervention sessions'*, will influence the reproducibility of the intervention in clinical practice. It was found that both aspects were described by 88.89% (n=8) of included RCTs. Interventions examples reported in the RCTs included goal-setting, problem solving, pain management, discussions, positive thinking, coping strategies, advice, body weight influence, education on exercises, anatomy. When the aspect *'description of the intervention procedure'* is broken down in to its two elements, it can be seen that one of the included RCTs (Hurley et al., 2007) did not report on the element *'procedure, activities, and/or processes'* and three RCTs (Kao et al., 2011; Hurley et al., 2007; Nuñez et al., 2006) did not report the element *'any enabling or supporting activities'*. The aspect *'details about the number, duration, intensity and dose of intervention sessions'* has five elements. The element *'number of times'* were reported in seven of the nine RCTs (Hinman et al., 2016; Da Silva et al., 2015; Hurley et al., 2012; Ravaued et al., 2009; Hurley et al., 2007; Yip et al., 2007; Nuñez et al., 2006) and the element *'duration, intensity or dose'* was reported in six RCTs (Da Silva et al., 2015; Coleman et al., 2012; Kao et al., 2011; Hurley et al., 2012; Yip et al., 2007; Nuñez et al., 2006). The element *'schedule of the sessions' (when the sessions take place)* were however only reported in three of the included RCTs (Da Silva et al., 2015; Hurley et al., 2012; Ravaued et al., 2009). Description was lacking on how long sessions last and how frequently sessions should be done. These are all factors affecting the patient's amount of clinic visiting. The financial burden should be considered when looking at the dosage or number of sessions provided, because patients will incur additional travelling costs due to visiting the clinic more often (Lorenzo et al., 2015).

The feature setting or location of the health care facility where the intervention will be administered, influences the service delivery (Visagiel & Schneider, 2014). The aspect *'location of intervention delivery and key infrastructure'* is unfortunately an aspect were the majority of the description was lacking from the included RCTs with not one RCT adequately describing all of the three relating elements *('type of location', 'necessary infrastructure' or 'relevant features'*) used for the intervention administration. The setting forms part of the format of the sessions and also plays a

role in the financial implications for patients in accessing the healthcare setting, the infrastructure needed to apply or administrate the intervention and the relevant features of the intervention (Lorenzo et al., 2015). There is no point in having a perfectly formulated intervention but no setting to provide it to patients. Interventions should be easily transferable (Duet et al., 2013).

Tailoring an intervention is dependent on a patient's local context, beliefs, profile, setting, work force and resources available (Kautzkyi & Tollmani, 2008). The aspect of *'description of details of any intervention tailoring'* is unfortunately not well reported within in the included RCTs as only three (Hurley et al., 2012; Ravaued et al., 2009, Hurley et al., 2007) reported on this aspect. The aspect can be divided in to five elements '*personalised, titrated or adapted', 'what', 'why', 'when' and 'how'*. As described in table 29, three RCTs (Hurley et al., 2012; Ravaued et al., 2009; Hurley et al., 2007) reported on the element '*personalised, titrated or adapted'*, while two RCTs (Hurley et al., 2012; Ravaued et al., 2009) reported on the element *'why'* and only one RCT (Ravaued et al., 2009) reported the *'how'* element of the aspect *'details of any intervention tailoring'*. No patient is alike and responds interventions differently (Duet et al., 2013). A *'one-size-fits-all'* approach is therefore not adequate (Duet et al., 2013). Interventions should be easily individualised, titrated and adapted to make it more usable for clinicians in any context (Duet et al., 2013). Intervention tailoring also enhances the reproducibility of an intervention when it aims to create an opportunity for adapting and contextualising of an intervention. When applying an intervention, policy, context and funding also need to be considered (Kautzkyi & Tollmani, 2008). For example interventions should be easily adapted, materials used should be easily converted or changed to fit the local contexts language and literacy, number of sessions adapted according the workforces and resources available. Just like tailoring, modifications reported in RCTs, should also be easily applied. It can be seen that none of the RCTs reported on the aspect *'any modifications throughout the study'*. Due to the lack of detail, the data is not transferable to clinical practice. The research of studies goes to loss by not being used, due to clinicians not being able to adapt interventions and research that was done, is "wasted" due to not being usable. Time and resources are wasted.

Self-help and education are two techniques where patients have to take responsibility of their own health for the intervention to be successful in enhancing patient health. Adherence to management therefore forms a critical part in not only curative aspects of therapy, but a preventative part as well (Mazières, Thevenon, Chevalier, Revel, & Rannou, 2008). Adherence of a treatment intervention can extend the effect of the treatment (Mazières et al., 2008). If the treatment effect is extended, potentially less contact treatment sessions is needed (Mazières et al., 2008). Therefore patients, who are unable to access PHC settings due to either financial or physical challenges, will have to visit PHC settings less often and benefit to adhere to post intervention self-help and education. When patients are needed to be treated less, a contribution towards lowering the economic burden will take place (Van Geertruyden et al., 2015; Sherry, 2014). Unfortunately the aspect *'details of intervention fidelity assessment monitoring'* and *'level achieved'* are not elaborated on. Although 100% (n=9) of the RCTs that the element *'adherence or fidelity was assessed'*, the rest of the four elements *'how'*, *'whom'* and *'strategies to maintain'* was reported poorly. Adherence can be measured through standardised outcome measures and maintained through goal setting. In this study it can be seen in table 32, examples are only given in two RCTs (Hinman et al., 2016; Da Silva et al., 2015) who reported on the element *'how'* and only one RCT (Coleman et al., 2012) reported on the element *'strategies to maintain'*. The poorly reported and described data again leaves a big gap on adherence for clinicians. Clinicians are left with no examples of how adherence can be increased.

This study has found good quality recent CPGs are available for OA knee, however both the latest, included CPGs were produced in developed countries. South Africa is still a developing country. As described in table 35, there are local contextual issues which could constrain the immediate uptake of recommendations as reported in the included RCTs. When considering issues involving the physiotherapist, it can be seen that work force shortage is a major concern and mentioned frequently. Four of the TIDieR aspects (*'details of intervention providers'*, *'description of intervention procedure'*, *'mode of delivery of intervention'* and *'details about the number, duration,*

intensity, and dose of intervention sessions') can be affected by workforce shortage. When considering the aspect *'location of intervention delivery and key infrastructure'*, one has to remember in areas where resources are scares, interventions will have to be able to be applied and carried out in any available setting. The aspects *'description of intervention procedure'*, *'mode of delivery of intervention'* and *'details of any intervention tailoring'* will have to bear in mind South Africa's diversity with 11 different languages which can create a barrier in delivering an intervention. When considering materials such as shoes and DVDs the probability to use it in the South African PHC setting for effective service delivery are small, due to the impacted that the availability of resources have on for promotional material. The aspect *'details of intervention tailoring'* and *'any intervention modifications throughout the study'* is again very important for reproducibility when involving South Africa's several different ethnic groups. South Africa has a vast variety of ethnic groups , all needing specific, tailored approaches.

For further considerations it would be interesting to investigate the experiences of clinicians who tried implementing CPGs. The clinicians can report on factors that either eased the use of the CPG or that created obstacles. By doing the investigation on a clinical level, the findings of the current study would be supported and further strengthened. The local context and setting of an area affects the intervention methods (Lorenzo et al., 2015) and therefore the investigation can also be done on different PHC settings. This could give an indication on how much interventions should be tailored, personalised or adapted to still be reproducible, but effective.

Another weakness of this study that a limitation leading to a gap, is that we still know little about the influence of the patient's own perceptions, beliefs and cultural groups in relation to a generic 'one-size-fits-all' approach for self-help and education as an intervention. The patients' influences together with the patients' expectations and interpretations can also be considered to be investigated. It can be done through interviews or questionnaires completed by patients.

Knee OA is one of the most common conditions treated by therapists on a PHC level (Allen et al., 2010). After all intervention methods in CPGs for adults suffering from knee OA are explored, other conditions that are prevalent on a community level (such as cerebral vascular accidents, lower back pain, cerebral palsy, rheumatoid arthritis and amputations) can be investigated. CPGs are available for each condition, but the same questions can be asked on how reproducible they are on a PHC level.

Economy and social structure can be elevated by adequate rehabilitation (Sherry, 2014). A factor that was not an outcome of this review is the direct economic impact of the interventions and the cost involved in applying the interventions in clinical practice. This leaves a gap for further investigation.

CHAPTER 6

CONCLUSION

The study reports on the evaluation of the descriptions of physiotherapy rehabilitation interventions, specifically self-help and education as management for adults with knee osteoarthritis (OA) as reported in clinical practice guidelines (CPGs). Despite the availability of evidence for the use of the self-help and education for knee OA, there remains a lack of detail in the descriptions of the interventions within the included randomised controlled clinical trials (RCTs). Since the reproducibility of an intervention in a clinical setting forms a crucial part of adding value to research, the lack of description and difficult in reproducing in clinical practice, is concerning. It implies that despite the continuous advocacy of evidence based practice, a lot still needs to be done to ensure true replication of evidence in practice. Although there is a lot of research available for the treatment of knee OA to contribute towards evidence based practice, the information in not clinically reproducible and therefore becomes unusable**.** CPGs therefore fail to bridge the gap between best practice, patient's preferences and therapists' skills and knowledge, and typically cannot be applied within every context. Strategies to address this gap need to be developed. The current information on self-help and education for patients with knee OA requires additional investment to ensure that it is reproducible in the South African primary health care setting (PHC) settings. As it stands it is not possible for a physiotherapist in a PHC setting in South Africa to readily adopt any of the CPG recommendations for self-help and education interventions for patients with knee OA.

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APPENDICES

Appendix A: Ethics Letter of Approval

UNIVERSITEIT
STELLENBOSCH
UNIVERSITY

Approved

New Application - Exemption

Health Research Ethics Committee (HREC)

08-Nov-2017

Ethics Reference #: X17/10/017

Project Ref No: 1522

Title: Project Title: Evaluation of the description of self-help and education as a physiotherapy rehabilitation intervention for adults with knee osteoarthritis and how it prohibits replication in the clinical practice

Dear Ms J Heyns

Your application for ethics exemption dated 13 October 2017 refers.

The Health Research Ethics Committee has assessed your application and considers this research proposal to meet the requirements for ethics exemption. This project involves secondary qualitative research based on information already available in the public domain.

This letter confirms that this research is now registered and you can proceed with study related activities.

Yours sincerely,

Frankiln Weber

HREC Coordinator,

Health Research Ethics Committee 1

Page 1 of 1

Appendix B: iCAHE Appraisal Tool

Availability	
Is the guideline readily available in full text?	(1)
Does the guideline provide a complete reference list?	(1)
Does the guideline provide a summary of its recommendations?	(1)
Dates	
Is there a date of completion available?	(1)
Does the guideline provide an anticipated review date	(1)
Does the guideline provide dates for when literature was included?	(1)
Underlying Evidence	
Does the guideline provide an outline of the strategy they used to find underlying evidence?	(1)
Does the guideline use a hierarchy to rank the quality of the underlying evidence?	(1)
Does the guideline appraise the quality of the evidence which underpins its recommendations?	(1)
Does the guideline link the hierarchy and quality of underlying evidence to each recommendation?	(1)
Guideline developers	
Are the developers of the guideline clearly stated?	(1)

Are the developers of the guideline clearly stated?	(1)
Guideline purpose and users	
Are the purpose and target users of the guideline stated?	(1)
Ease of use	
Is the guideline readable and easy to navigate?	(1)
Score	TOTAL /14

Appendix C: PEDro Scale

1.	eligibility criteria were specified	no ❑ yes ☒ where:
2.	subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	no ☒ yes ❑ where:
3.	allocation was concealed	no ☒ yes ❑ where:
4.	the groups were similar at baseline regarding the most important prognostic indicators	no ☒ yes ❑ where:
5.	there was blinding of all subjects	no ☒ yes ❑ where:
6.	there was blinding of all therapists who administered the therapy	no ☒ yes ❑ where:
7.	there was blinding of all assessors who measured at least one key outcome	no ❑ yes ☒ where:
8.	measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	no ❑ yes ☒ where:
9.	all subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by "intention to treat"	no ☒ yes ❑ where:
10.	the results of between-group statistical comparisons are reported for at least one key outcome	no ❑ yes ☒ where:
11.	the study provides both point measures and measures of variability for at least one key outcome	no ❑ yes ☒ where:

The PEDro scale is based on the Delphi list developed by Verhagen and colleagues at the Department of Epidemiology, University of Maastricht (*Verhagen AP et al (1998). The Delphi list: a criteria list for quality assessment of randomised clinical trials for conducting systematic reviews developed by Delphi consensus. Journal of Clinical Epidemiology, 51(12):1235-41*). The list is based on "expert consensus" not, for the most part, on empirical data. Two additional items not on the Delphi list (PEDro scale items 8 and 10) have been included in the PEDro scale. As more empirical data comes to hand it may become possible to "weight" scale items so that the PEDro score reflects the importance of individual scale items.

The purpose of the PEDro scale is to help the users of the PEDro database rapidly identify which of the known or suspected randomised clinical trials (i.e. RCTs or CCTs) archived on the PEDro database are likely to be internally valid (criteria 2-9), and could have sufficient statistical information to make their results interpretable (criteria 10-11). An additional criterion (criterion 1) that relates to the external validity (or "84eneralizability" or "applicability" of the trial) has been retained so that the Delphi list is complete, but this criterion will not be used to calculate the PEDro score reported on the PEDro web site.

The PEDro scale should not be used as a measure of the "validity" of a study's conclusions. In particular, we caution users of the PEDro scale that studies which show significant treatment effects and which score highly on the PEDro scale do not necessarily provide evidence that the treatment is clinically useful. Additional considerations include whether the treatment effect was big enough to be clinically worthwhile, whether the positive effects of the treatment outweigh its negative effects, and the cost-effectiveness of the treatment. The scale should not be used to compare the "quality" of trials performed in different areas of therapy, primarily because it is not possible to satisfy all scale items in some areas of physiotherapy practice.

Notes on administration of the PEDro scale:

All criteria	**Points are only awarded when a criterion is clearly satisfied**. If on a literal reading of the trial report it is possible that a criterion was not satisfied, a point should not be awarded for that criterion.
Criterion 1	This criterion is satisfied if the report describes the source of subjects and a list of criteria used to determine who was eligible to participate in the study.
Criterion 2	A study is considered to have used random allocation if the report states that allocation was random. The precise method of randomisation need not be specified. Procedures such as coin-tossing and dice-rolling should be considered random. Quasi-randomisation allocation procedures such as allocation by hospital record number or birth date, or alternation, do not satisfy this criterion.
Criterion 3	*Concealed allocation* means that the person who determined if a subject was eligible for inclusion in the trial was unaware, when this decision was made, of which group the subject would be allocated to. A point is awarded for this criteria, even if it is not stated that allocation was concealed, when the report states that allocation was by sealed opaque envelopes or that allocation involved contacting the holder of the allocation schedule who was "off-site".
Criterion 4	At a minimum, in studies of therapeutic interventions, the report must describe at least one measure of the severity of the condition being treated and at least one (different) key outcome measure at baseline. The rater must be satisfied that the groups' outcomes would not be expected to differ, on the basis of baseline differences in prognostic variables alone, by a clinically significant amount. This criterion is satisfied even if only baseline data of study completers are presented.
Criteria 4, 7-11	*Key outcomes* are those outcomes which provide the primary measure of the effectiveness (or lack of effectiveness) of the therapy. In most studies, more than one variable is used as an outcome measure.
Criterion 5-7	*Blinding* means the person in question (subject, therapist or assessor) did not know which group the subject had been allocated to. In addition, subjects and therapists are only considered to be "blind" if it could be expected that they would have been unable to distinguish between the treatments applied to different groups. In trials in which key outcomes are self-reported (eg, visual analogue scale, pain diary), the assessor is considered to be blind if the subject was blind.
Criterion 8	This criterion is only satisfied if the report explicitly states *both* the number of subjects initially allocated to groups *and* the number of subjects from whom key outcome measures were obtained. In trials in which outcomes are measured at several points in time, a key outcome must have been measured in more than 85% of subjects at one of those points in time.
Criterion 9	An *intention to treat* analysis means that, where subjects did not receive treatment (or the control condition) as allocated, and where measures of outcomes were available, the analysis was performed as if subjects received the treatment (or control condition) they were allocated to. This criterion is satisfied, even if there is no mention of analysis by intention to treat, if the report explicitly states that all subjects received treatment or control conditions as allocated.
Criterion 10	A *between-group* statistical comparison involves statistical comparison of one group with another. Depending on the design of the study, this may involve comparison of two or more treatments, or comparison of treatment with a control condition. The analysis may be a simple comparison of outcomes measured after the treatment was administered, or a comparison of the change in one group with the change in another (when a factorial analysis of variance has been used to analyse the data, the latter is often reported as a group × time interaction). The comparison may be in the form hypothesis testing (which provides a "p" value, describing the probability that the groups differed only by chance) or in the form of an estimate (for example, the mean or median difference, or a difference in proportions, or number needed to treat, or a relative risk or hazard ratio) and its confidence interval.

Criterion 11 A *point measure* is a measure of the size of the treatment effect. The treatment effect may be described as a difference in group outcomes, or as the outcome in (each of) all groups. *Measures of variability* include standard deviations, standard errors, confidence intervals, interquartile ranges (or other quantile ranges), and ranges. Point measures and/or measures of variability may be provided graphically (for example, SDs may be given as error bars in a Figure) as long as it is clear what is being graphed (for example, as long as it is clear whether error bars represent SDs or Ses). Where outcomes are categorical, this criterion is considered to have been met if the number of subjects in each category is given for each group.

Appendix D: TIDieR Evaluating Tool

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
	BRIEF NAME		
1.	Provide the name or a phrase that describes the intervention.	_____	_____
	WHY		
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.	_____	_____
	WHAT		
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	_____	_____
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	_____	_____

	WHO PROVIDED		
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	_____	_____
	HOW		
6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	_____	_____
	WHERE		
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	_____	_____
	WHEN and HOW MUCH		
8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	_____	_____
	TAILORING		
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	_____	_____
	MODIFICATIONS		
10.‡	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	_____	_____
	HOW WELL		
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies	_____	_____

	were used to maintain or improve fidelity, describe them.		
12.‡	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	_____	_____

12. ** **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use '?' if information about the element is not reported/not sufficiently reported.
13. † If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).
14. ǂ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.
15. * We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement.** When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013 Statement** (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see www.equator-network.org