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Physical activity and education about physical activity for chronic musculoskeletal pain in children and adolescents (Protocol)

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TABLE OF CONTENTS

[Intervention Protocol]

Physical activity and education about physical activity for chronic musculoskeletal pain in children and adolescents

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ABSTRACT

This is a protocol for a Cochrane Review (Intervention). The objectives are as follows:

To evaluate the effectiveness of physical activity or education about physical activity, or both, compared to active medical care, waiting list, or usual care in children and adolescents with chronic musculoskeletal pain.

BACKGROUND

Description of the condition

Chronic pain (i.e. pain lasting longer than three months) is responsible for major socioeconomic burden and affects about one-third of the population worldwide (Elzahaf 2012; Harstall 2003). Chronic pain is prevalent in children and adolescents, as well as adults (Rathleff 2017). The worldwide prevalence of chronic pain in children and adolescents is around 20%, and musculoskeletal conditions represent a large proportion (Henschke 2014; King 2011). There is evidence that musculoskeletal conditions are also a major contributor to disability in this population, with increasing rates of disability with age (Global 2016; Murray 2013). Chronic pain is also associated with an economic burden to society, although the availability of these data are limited; for example the national cost of pediatric chronic pain in the USA has been estimated as USD 19.5 billion annually (Groenewald 2014).

Among the different conditions that can lead to disabling musculoskeletal pain, the most commonly seen in children and adolescents are back pain, neck pain, upper limb pain and sports injuries. Among those, low back pain is among the most prevalent in children and adolescents (Akdag 2011), with a monthly prevalence of 37% reported in a large study of 404,206 children from 28 countries (Swain 2014). The prevalence of neck pain, upper limb pain and lower limb pain has been reported as 28%, 8%, and 15%, respectively (Jeffries 2007; Picavet 2016). The region of the body seems, however, to have little influence on the impact of pain in children's lives (Dunn 2011). Children and adolescents with chronic pain report higher levels of disability, lower mood, and socialise less with their friends. There is evidence that children and adolescents recognise pain as an obstacle to doing exercise and participating in physical activities, which can result in school absenteeism and overall poor health in adult life (Roth-Isigkeit 2005; Wilson 2010).

The experience of persistent pain in childhood may have important consequences in adult life. Children with chronic pain have an increased likelihood of developing other painful conditions, such as back pain, headaches, and abdominal pain, in adulthood (Dunn 2011; Harreby 1995). For example, children who experience low back pain in adolescence are 3.5 times more likely to experience the condition in adult life (Hestbaek 2006). Other adverse consequences in adulthood for children who suffer from musculoskeletal pain include higher risk of obesity (Paulis 2014), smoking habits (Shiri 2010), mental health disorders (Hainsworth 2012; Noel 2016), and increased risk of suicide (van Tilburg 2011).

Description of the intervention

Chronic musculoskeletal pain in children is clinically managed with conservative treatments for the majority of cases (Kamper 2016). Among the most commonly used interventions are physical activity (including exercise) and education about physical activity. In people with chronic pain, physical activity and education can be delivered independently or in combination, to address the complexity of the symptoms in people with chronic pain (Friedrichsdorf 2016).

Physical activity

Physical activity is defined as any bodily movement produced by skeletal muscles that results in energy expenditure. It can be categorised into occupational, sports, conditioning, household, or other activities. It includes all forms of activity, such as everyday walking or cycling, active play, active recreation (e.g. working out in a gym), dancing, gardening or playing active games, exercise, and organised and competitive sports (WHO 2015). Exercise is considered a subset of physical activity that is planned, structured and repetitive and has a final or an intermediate objective of improvement or maintenance of physical fitness (i.e. attributes that are either health- or skill-related), which can be performed with or without supervision (Caspersen 1985; Stay Active Report 2011).

Education about physical activity

Education is a mainstay of medical care. Education related to physical activity can be defined as the process of providing information with the aim to increase knowledge and understanding about physical activity, sedentary behaviour or lifestyle, in order to build a person's internal resources to maintain participation in their valued activities and avoid inactivity. This can be delivered by healthcare professionals, parents and carers (after previous training), or via printed materials (e.g. booklet, folder) or telecommunication networks (e.g. website, app).

How the intervention might work

Physical activity

While mechanisms of effect in musculoskeletal pain are not well understood for these interventions a number of theoretical models have been proposed including cognitive, behavioural and biomechanical models. There is evidence that exercise and physical activity act on physical and psychological mechanisms to reduce pain and disability (e.g. fear-avoidance belief model). These may have influences at the cognitive level in terms of reducing fear and anxiety related to pain and movement, and also build physical strength and endurance (Smith 2018). Supervised exercise has been reported as an effective intervention for reducing pain compared to no treatment (Kamper 2017; Michaleff 2014); however, the quality of evidence related to physical activity interventions is often low (Kamper 2017).

Education about physical activity

Recent studies show that educational interventions may be effective in improving knowledge about pain, but have limited or no effect on reducing pain intensity alone (Lynch-Jordan 2014). Educational interventions aimed at increasing knowledge and understanding of physical activity have the potential to benefit children and adolescents with chronic musculoskeletal non-cancer pain due to their lower level of physical activity (Friedrichsdorf 2016; Kamper 2017; Wilson 2012). Further, physical activity combined with education about physical activity are more likely to be effective in reducing pain when compared to home exercise, advice or no treatment (Kamper 2017).

Why it is important to do this review

Chronic musculoskeletal pain is a prevalent condition during childhood and negatively impacts the lives of children and adolescents. Their chronic musculoskeletal pain is usually managed with physical activity or education about physical activity, or both, and most commonly these approaches are delivered as part of a complex intervention (i.e. multicomponent interventions). To date, there is no high-quality synthesis of research on physical activity or education about physical activity,

or both, thus a Cochrane Review is needed to inform clinicians, patients, parents and carers, and policy makers.

OBJECTIVES

To evaluate the effectiveness of physical activity or education about physical activity, or both, compared to active medical care, waiting list, or usual care in children and adolescents with chronic musculoskeletal pain.

METHODS

Criteria for considering studies for this review

Types of studies

We will include randomised controlled trials (RCTs) or cross-over controlled trials that deliver physical activity or education about physical activity, or both, to children and adolescents with chronic musculoskeletal pain. We will exclude studies that are not randomised, including quasi-randomised trials, controlled trials, and case series.

Types of participants

We will consider studies that include children and adolescents of school age (4 to 18 years) with any chronic musculoskeletal pain (e.g. neck or back pain, shoulder pain, knee pain, widespread pain/fibromyalgia, neuropathic pain, complex regional pain syndrome and juvenile idiopathic arthritis). Chronic pain is defined as any pain that has lasted more than three months. We will include studies on children and adolescents with musculoskeletal pain and other pain complaints (e.g. back pain and headache). We will consider including studies of children and adolescents with mixed pain conditions (e.g. headache and abdominal pain) if data for chronic musculoskeletal pain are available separately or if they correspond to at least 75% of the sample. We will consider including studies of mixed populations of children and adults if the study presents data for children or adolescents separately. We will exclude studies that include participants with cancer-related pain, or isolated headaches, migraine or visceral (e.g. abdominal) pain. We will exclude studies that include participants receiving palliative care.

Types of interventions

We will include studies of interventions involving physical activity or education about physical activity, or both, as a key component. We will consider educational interventions related to physical activity, sedentary behaviour and lifestyle. The educational intervention must be delivered as a standalone intervention, and not as part of another intervention. For example, we will not include education that forms part of a broader psychological intervention (e.g. cognitive behavioural therapy, acceptance and commitment therapy) or is part of a neuroscience pain education intervention. Information can be delivered by healthcare professionals, parents or carers (after previous training) or via printed materials (e.g. booklet, folder) or media (e.g. website). We will exclude multi-component interventions where physical activity is combined with another intervention and the effect of physical activity cannot be isolated from the other intervention (e.g. physical activity and diet versus usual care).

Comparators

We will accept studies where the comparison group is provided with active medical care, waiting list, or usual care including minimal interventions such as advice, relaxation classes, or social group meetings. We will also include studies where multiple participant groups receive the same non-exercise treatment, for example physical activity plus usual care versus usual care alone.

Types of outcome measures

We will assess outcomes at the post-intervention assessment (i.e. the first assessment point after end of treatment and no longer than 3 months), and long-term follow-up (closest to 12 months after the intervention).

Primary outcomes

- Pain intensity measured using a visual analogue scale (VAS), numerical rating scale (NRS), verbal rating scale, questionnaire or Likert scale. We will also consider other pain assessments that are commonly used for young age groups, such as facial or verbal expression, movements, posture, and interaction with the environment
- Disability measured using a self-reported outcome measure, including generic and condition-specific measurement tools (e.g. Functional Disability Inventory, PedsQL)
- Adverse events (incidence and nature)

Secondary outcomes

- Depression (measured by any reliable and valid instrument, e.g. Children's Depression Inventory)
- Anxiety (measured by any reliable and valid instrument, e.g. Revised Child Anxiety and Depression Scale)
- Fear avoidance (measured by any reliable and valid instrument, e.g. Fear of Pain Questionnaire Child)
- Quality of life (measured by any reliable and valid instrument, including generic and condition specific measurement tools, e.g. Pediatric Quality of Life Inventory)
- Physical activity level (measured objectively, i.e. accelerometers or pedometers, or self-reported with validated questionnaires)
- Caregiver distress (measured by any reliable and valid instrument, e.g. Caregiver Well-Being Scale)

Search methods for identification of studies

Electronic searches

We will search the following databases with no restrictions placed on language or year of publication.

- The Cochrane Central Register of Controlled Trials (CENTRAL, in the Cochrane Library)
- MEDLINE (via OvidSP)
- Embase (via OvidSP)
- Cumulative Index to Nursing and Allied Health Literature (CINAHL) (EBSCO)
- PsycINFO (via OvidSP)
- Physiotherapy Evidence Database (PEDro)
- Latin American and Caribbean Health Sciences Literature (LILACS)

We will use MeSH or equivalent and text word terms. We will tailor searches to individual databases. The search strategy for MEDLINE is in Appendix 1.

Searching other resources

We will search ClinicalTrials.gov and the World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP: apps.who.int/trialsearch) for ongoing trials. In addition, we will check reference lists of reviews and retrieved articles for additional studies and we will perform citation searches on key articles. We will contact study authors for additional information where necessary.

Data collection and analysis

Selection of studies

Two review authors (TPY and PVS) will independently determine eligibility by reading the title and abstract of each study identified by the search. They will eliminate studies that clearly do not satisfy inclusion criteria, and obtain full copies of the remaining studies. Any disagreements that cannot be resolved by discussion between the two authors doing the initial screening will be subject to arbitration by a third author (SK). Two review authors (TPY and PVS) will independently read the full texts of the studies they have selected to identify eligible studies and resolve conflicts by discussion; in the event of disagreement a third author will adjudicate. We will include a PRISMA flow chart in the full review which will show the status of identified studies (Moher 2009), as recommended in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2019).

Data extraction and management

Two review authors will independently extract data using a standardised piloted form and check for agreement before entry into Review Manager 5 (RevMan 5) (Review Manager 2014). In the event of disagreement, a third author will adjudicate. We will extract the following information.

- Bibliometric data (authors, year of publication, language)
- Study characteristics (study design, sample size, description of the sample, country, recruitment year(s) and procedure, conflict of interest, funding source)
- Characteristics of the participants (gender, age, condition, duration of pain)
- Description of the interventions (experimental and control), according to the TIDieR checklist (Appendix 2)
- Duration of follow-up
- Outcome measures of interest
- Time periods of outcome assessment

We will collate multiple reports of the same study, so that each study rather than each report is the unit of interest in the review. We will collect characteristics of the included studies in sufficient detail to populate a table of 'Characteristics of included studies' in the full review.

Assessment of risk of bias in included studies

Two authors will independently assess risk of bias for each study, using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2019), with any disagreements resolved by discussion or a third author if necessary. We will complete a 'Risk of bias' table for each included study using the 'Risk of bias' tool in Review Manager 2014.

We will assess the following for each study.

- Selection bias
  - Random sequence generation: we will assess the method used to generate the allocation sequence as: low risk of bias (any truly random process, e.g. random number table; computer random number generator); unclear risk of bias (method used to generate sequence not clearly stated). We will exclude studies using a non-random process (e.g. alternation, odd or even date of birth; hospital or clinic record number).
  - Allocation concealment: the method used to conceal allocation to interventions prior to assignment determines whether intervention allocation could have been foreseen in advance of or during recruitment, or changed after assignment. We will assess the methods as: low risk of bias (e.g. telephone or central randomisation; consecutively numbered sealed opaque envelopes); unclear risk of bias (method not clearly stated). We will exclude studies that do not conceal allocation (e.g. open list).
- Performance bias
  - Treatment expectations: it is often not possible to blind study participants and personnel in pragmatic studies that evaluate physical activity interventions. Therefore, following Cochrane Pain, Palliative and Supportive Care (PaPaS) Review Group guidance, we will assess treatment expectations between groups at baseline. We will consider studies to have low risk of bias if they report expectations or treatment credibility between groups as equal. We will consider studies to have high risk of bias when differences are reported in trials between groups; and rate studies as unclear risk of bias when studies do not describe baseline expectations between treatment and control group.
- Detection bias
  - Blinding of outcome assessment: we will assess the methods used to blind outcome assessors from knowledge of which intervention a participant received. We will assess the methods as: low risk of bias (study has a clear statement that outcome assessors were unaware of treatment allocation, and ideally describes how this was achieved); unclear risk of bias (study states that outcome assessors were blind to treatment allocation but lacks a clear statement on how it was achieved); high risk of bias (outcome assessors were not blinded to group allocation or study did not provide information on blinding of outcome assessors). We will consider studies to have unclear risk of bias for patient-reported outcomes since participants cannot be blinded.
- Attrition bias
  - Incomplete outcome data: we will assess attrition bias by considering if participant dropout rate was appropriately described and acceptable: low risk of bias (less than 10% dropout and appeared to be missing at random; numbers given per group and reasons for dropout described); unclear risk of bias (if less than 20% but reasons not described and numbers per group not given; unclear that data were missing

at random); high risk of bias (if over 20% even if imputed appropriately).
    * Intention-to-treat analysis: we will assess whether participants were analysed in the group to which they were allocated as: low risk of bias (if analysed data in group to which originally assigned with appropriately imputed data or as an available-case analysis); unclear risk of bias (insufficient information provided to determine if analysis was per protocol or intention to treat); high risk of bias (if per-protocol analysis used; where available data were not analysed or participant data were included in group they were not originally assigned to).
- Reporting bias
    * Selective reporting: we will assess whether primary and secondary outcome measures were pre-specified (e.g. trial protocol, trial registry) and whether these were consistent with those reported: low risk of bias (all the results from all pre-specified outcomes were adequately reported in the published report of the trial; or in the absence of the protocol, assessing that the published report includes enough information to make this judgment); high risk of bias (no protocol publicly available); unclear risk of bias (no mention of protocol and published report does not include enough information to make a judgment).
- Other sources of bias
    * Groups' similarity at baseline (potential bias arising by chance with random allocation): low risk of bias (groups have to be similar at baseline regarding demographic factors, duration and severity of complaints, and value of main outcome measures); unclear risk of bias (not enough information regarding baseline factors); high risk of bias (groups are clearly different at baseline regarding the most important prognostic factors).

Measures of treatment effect

We will analyse pain intensity and present on a continuous scale from 0 to 100 as mean differences (MDs) and 95% confidence intervals (CIs). For the other continuous outcomes (e.g. disability, quality of life), we will quantify the treatment effects with standardised mean difference (SMD) and 95% CIs, as trials often use different measurement scales to assess these outcomes. We will consider between-group differences of at least 10% of the scale as clinically important (Busse 2015; Saragiotto 2016). To facilitate interpretation, we will also translate pooled SMD values to the equivalent in commonly used scales, using the standard deviation reported in the included studies.

We also expect to encounter dichotomous outcomes. For dichotomised data (responder analyses), we will consider analyses based upon a 30% or greater reduction in pain intensity to represent a moderately important benefit, and a 50% or greater reduction in pain intensity to represent a substantially important benefit as suggested by the IMMPACT guidelines (Dworkin 2008). In such cases, we will calculate the risk ratios (RRs), and number needed to treat for an additional beneficial outcome (NNTB) for experiencing the positive outcome.

Unit of analysis issues

Randomisation will occur at the individual level. To deal with repeated observations on participants we will follow the strategy of defining the outcomes (stated previously) as well as the time points a priori (Higgins 2019). If studies include multiple treatment arms, we will form multiple treatment comparisons but if there is a shared group we will split this in order to be able to include two (reasonably independent) comparisons.

Dealing with missing data

We will contact authors requesting any necessary data that are not reported or are unclear in the manuscript. In cases where data are reported as a median and interquartile range (IQR), we will assume that the median is equivalent to the mean and the width of the IQR is equivalent to 1.35 times the standard deviation (Higgins 2019). We will also estimate data from graphs if this information is not presented in tables or text. If any information regarding standard deviations is missing, we will calculate these from confidence intervals or standard errors (if available) of the same study. We will estimate the standard deviation from the most similar trial in the review, if no measure of variability is presented anywhere in the text, taking into consideration the study population, size and the risk of bias.

Assessment of heterogeneity

We will base the assessment of heterogeneity upon visual inspections of the forest plots (e.g. overlapping confidence intervals) and more formally by the Chi^2 test and the I^2 statistic as recommended in the *Cochrane Handbook for Systematic Reviews of Interventions (*Higgins 2019). We will interpret heterogeneity as:

- 0% to 40%; might not be important;
- 30% to 60%; may represent moderate heterogeneity;
- 50% to 90%; may represent substantial heterogeneity;
- 75% to 100%; considerable heterogeneity.

Assessment of reporting biases

We will perform comprehensive searches in order to reduce the possibility of reporting biases. We plan to use funnel plots to visually explore the likelihood of reporting biases when there are at least 10 studies in a meta-analysis and included studies differ in size; and we will use Egger's test to detect possible small-study bias. We will not add any language restriction to our search strategy in order to avoid potential language bias.

Data synthesis

We will combine the results from individual trials through meta-analysis using random-effects models. We will use intention-to-treat analysis preferably over per-protocol or as-treated analysis. We will use RevMan 5 for all analyses (Review Manager 2014). The time points will be categorised as 'post-intervention' (i.e. the first assessment point after end of treatment and no longer than 3 months), and 'long-term follow-up' (closest to 12 months after the intervention).

We will conduct the following comparisons.

- Physical activity vs. usual care (post-intervention)
- Physical activity vs. usual care (follow-up)
- Physical activity vs. active medical care (post-intervention)
- Physical activity vs. active medical care (follow-up)
- Physical activity vs. waiting list (post-intervention)
- Physical activity vs. waiting list (follow-up)

- Education vs. usual care (post-intervention)
- Education vs. usual care (follow-up)
- Education vs. active medical care (post-intervention)
- Education vs. active medical care (follow-up)
- Education vs. waiting list (post-intervention)
- Education vs. waiting list (follow-up)
- Physical activity and education vs. usual care (post-intervention)
- Physical activity and education vs. usual care (follow-up)
- Physical activity and education vs. active medical care (post-intervention)
- Physical activity and education vs. active medical care (follow-up)
- Physical activity and education vs. waiting list (post-intervention)
- Physical activity and education vs. waiting list (follow-up)

Quality of the evidence

We will assess the overall quality of the evidence for each outcome using the GRADE approach, as recommended in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2019). Two review authors (TPY and SK) will independently rate the quality of the outcomes. Five factors that may decrease the quality of the evidence are:

- study design and risk of bias (downgraded if more than 25% of the participants are from studies with a high risk of bias (one or more bias domains judged as high risk of bias, except performance bias);
- inconsistency of results (downgraded if significant heterogeneity is present by visual inspection or if the I^2 value was greater than 50%);
- indirectness (generalisability of the findings; downgraded if more than 50% of the participants are outside the target group);
- imprecision (downgraded if fewer than 400 participants are included in the comparison for continuous data or there are fewer than 300 events for dichotomous data (Mueller 2007));
- publication bias.

We will consider single studies with fewer than 400 participants for continuous or dichotomous outcomes inconsistent and imprecise, providing 'low-quality evidence', which could be downgraded to 'very low quality evidence' if there are further limitations on the quality of evidence (Saragiotto 2016). We will reduce the quality of the evidence for a specific outcome by one level, according to the performance of the studies against the five factors above, and we will describe them as follows. If there are multiple serious limitations for one domain we will consider downgrading the quality of evidence by two levels for that domain, except for publication bias which can only be downgraded by one level.

The GRADE system uses the following criteria for assigning grade of evidence.

- High: we are very confident that the true effect lies close to that of the estimate of the effect
- Moderate: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of effect, but there is a possibility that it is substantially different
- Low: our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect
- Very low: we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect

'Summary of findings' table

We will include 'Summary of findings' tables as recommended in Section 4.6.6 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2019). There will be three tables, reflecting the three main comparisons in this review: physical activity versus usual care; education versus usual care; and physical activity plus education versus usual care. The 'Summary of findings' tables will include the following outcomes: pain intensity; disability; adverse events; depression; anxiety; and quality of life for post-intervention assessment. We will include key information concerning the quality of evidence, the magnitude of effect and the sum of available data on the outcomes.

Subgroup analysis and investigation of heterogeneity

We will conduct separate subgroup analyses for the type of intervention and conditions using the following subgroup definitions.

- Exercise, defined as a subset of physical activity that is planned, structured, and repetitive and has a final or an intermediate objective of improvement or maintenance of physical fitness (i.e. attributes that are either health- or skill-related) performed with or without supervision (Caspersen 1985; Stay Active Report 2011). We will categorise the exercise programmes (aerobic, strengthening, stretching, coordination, mixed) and if we find sufficient number of trials, we will perform a subgroup analysis. The planned comparisons are exercise vs. usual care, exercise vs. active medical care, and exercise vs. waiting-list, all for both post-intervention and long-term follow-up
- Region of pain (e.g. spinal, limb, multi-site, widespread/fibromyalgia)
- Specific diagnoses (e.g. juvenile idiopathic arthritis)

We will only perform subgroup analyses on primary outcomes and only if sufficient data are available.

Sensitivity analysis

We plan to perform sensitivity analyses to assess the influence of risk of bias on the overall estimates of treatment effects. We will compare effect sizes from meta-analyses including only studies with overall low or unclear risk of bias for the primary outcomes (i.e., low or unclear risk of bias for all key domains). We will consider studies having an overall high risk of bias if they are rated as high risk of bias on a single domain (except performance bias). We will also perform a sensitivity analysis by sample size, including studies with at least 50 participants per arm, or 100 in total (Geenen 2017).

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APPENDICES

Appendix 1. MEDLINE search strategy

1 MUSCULOSKELETAL PAIN/

2 exp Complex Regional Pain Syndromes/

3 Chronic Pain/

4 Fibromyalgia/

5 exp Neuralgia/

6 Arthritis, Juvenile/

7 (((chronic or long-term or musculoskeletal or joint*) adj3 pain*) or fibromyalgia or arthritis).tw.

8 or/1-7

9 adolescent/ or child/

10 (child* or boy* or girl* or teenage* or adolescen* or schoolchild* or juvenil*).tw.

11 9 or 10

12 exp ADULT/ or YOUNG ADULT/

13 11 not 12

14 exp Exercise/

15 health education/ or patient education as topic/ or "physical education and training"/

16 exp Exercise Therapy/

17 (educat* or exercise* or physical activit*).tw.

18 14 or 15 or 16 or 17

19 8 and 13 and 18

20 randomized controlled trial.pt.

21 controlled clinical trial.pt.

22 randomized.ab.

23 placebo.ab.

24 drug therapy.fs.

25 randomly.ab.

26 trial.ab.

27 groups.ab.

28 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27

29 exp animals/ not humans.sh.

30 28 not 29

31 19 and 30

Appendix 2. Template for Intervention Description and Replication (TIDieR) checklist

	Item	Where located?
	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	

(Continued)

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.

N/A: if an item is 'not applicable' for the intervention being described.

† 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).

‡ 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.

CONTRIBUTIONS OF AUTHORS

Draft the protocol	All authors

DECLARATIONS OF INTEREST

TPY: none known.

SJK: none known.

NEO: none known. Since NEO is an author as well as a PaPaS Co-ordinating Editor, we acknowledge the input of Christopher Eccleston who acted as Sign Off Editor for this review. NEO had no input into the editorial decisions or processes for this review.

ZAM: none known.

EF: none known.

PVS: none known.

CMW: none known.

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