**Context effects and behaviour change techniques in randomised trials: A systematic review using the example of trials to increase adherence to physical activity in musculoskeletal pain**

Felicity L Bishop\*1, Anya L Fenge-Davies1, Sarah Kirby1, Adam WA Geraghty2

\*Corresponding Author. F.L.Bishop@southampton.ac.uk. Tel: +44 (0)23 8059 9020. Address: Centre for Applications of Health Psychology, Faculty of Social and Human Sciences, Building 44 Highfield Campus, University of Southampton, Southampton SO17 1BJ United Kingdom.

**Affiliations**

1 Centre for Applications of Health Psychology, University of Southampton, Southampton, UK.

2 Primary Care and Population Sciences, University of Southampton, Southampton, UK.

**Abstract**

Objective: To describe and explore the effects of contextual and behaviour change technique (BCT) content of control and target interventions in clinical trials.

Design: Review and meta-analysis of 42 trials from a Cochrane review of physical activity in chronic musculoskeletal pain (Jordan, Holden, Mason, & Foster, 2010).

Main Outcome Measures: Two researchers coded descriptions of target and control interventions for (a) 93 BCTs and (b) whether target and control interventions shared each of 5 contextual features (practitioners’ characteristics, patient-practitioner relationship, intervention credibility, superficial treatment characteristics e.g. delivery modality, and environment). Quality of study reporting was assessed. Effect sizes for adherence to physical activity and class attendance were computed (Cohen’s d) and analysed separately.

Results: For physical activity outcomes, after controlling for reporting quality, larger effect sizes were associated with target and control interventions using different modalities (B = -.34, p=.030), target and control interventions involving equivalent patient-practitioner relationship (B=.40, p=.002), and target interventions having more unique BCTs (i.e. more BCTs not also in the control) (B=.008, p=.030). There were no significant effect moderators for class attendance outcomes.

Conclusion: Contents of control conditions can influence effect sizes and should be considered carefully in trial design and systematic reviews.

Keywords: methodology; control groups; trial design; behaviour change techniques; placebo effects; physical activity

In trials of health behaviour change interventions, the choice of control intervention constitutes one of many potential sources of bias. Indeed, the inferences that can be made about a target intervention following a randomised controlled trial (RCT) are crucially determined by the contents of the control intervention (Mohr et al., 2009). In conventional pharmaceutical trials designed to test the efficacy of a new drug, the only difference between a good control and a target intervention should be the active ingredients hypothesized to produce benefit. This model works well for drug trials: the active ingredients can be identified pharmacologically and are conceptualised as the source of so-called “specific” effects of the new drug. Everything else that happens to a patient in the trial is then considered a source of “non-specific”, “placebo” or “context” effects[[1]](#footnote-1) which need to be controlled for to maximise the trial’s internal validity and reduce risk of bias. Evidence from systematic reviews, trials, and meta-analyses confirms that clinically significant effects are produced by contextual factors including patients’ expectations (Crow et al., 1999; Benedetti & Amanzio, 2011), the therapeutic relationship (Di Blasi, Harkness, Ernst, Georgiou, & Kleijnen, 2001; Kaptchuk et al., 2008) and the physical environment (Drahota et al., 2012). Thus, if context effects are not considered when designing control conditions, researchers may unwittingly bias trials in favour of the target intervention. This paper briefly reviews approaches to context effects in medical and psychotherapy trials before considering control interventions in health behaviour change trials.

Five major domains of context effects have been identified (Di Blasi et al., 2001) and steps can be taken to reduce their confounding influence in drug trials. The influence of the practitioner (1) and the therapeutic relationship (2) can be minimised by using health care practitioners of equivalent experience and qualifications, blinding them to treatment allocation, training them to deliver consultations consistently, and randomly allocating individual patients to them. The influence of patients’ expectations (3) and superficial treatment characteristics (e.g. modality, colour or size of drugs) (4) can be reduced by randomisation and blinding patients to treatment allocation by using active placebo controls which are well-matched to the real drug (e.g. in dosage, colour, and side-effects). The influence of the environment (5) can be minimised by ensuring real and placebo interventions are delivered in the same settings.

Designing control interventions for RCTs involves a complex process of trade-offs between internal and external validity (Freedland, Mohr, Davidson, & Schwartz, 2011). Some options generally increase external validity but decrease internal validity (e.g. usual care controls; Freedland et al., 2011) while others generally increase internal validity but decrease external validity (e.g. contextual or “non-specific” controls; Mohr et al., 2009). Ultimately, choice of control intervention should be driven by the research question, and in some cases controlling for all contextual processes might not be appropriate.

In psychotherapy research, it has been conceptually and practically challenging to follow the biomedical model and isolate active ingredients from contextual components. The patient-practitioner relationship might be mere context in a drug trial, but in psychotherapy trials elements of the patient-practitioner relationship can be central to theorised change processes. These fundamental differences between drug therapy and psychotherapy provide the conditions for intense debate about choice of controls, the appropriateness of RCT methodology, and the relative contribution of specific and contextual effects to psychotherapy outcomes (Kirsch, 2005; Ahn & Wampold, 2001; Wampold et al., 1997; Luborsky et al., 2002). For example, Baskin et al (2003) argued that RCTs of psychological interventions should use controls that have structural equivalence with the target intervention, where structural equivalence includes such features as the duration, intensity, and credibility of an intervention. Meta-analysis showed that psychotherapy trials with structurally equivalent controls produced only negligible effects, demonstrating the strength of context effects in psychotherapeutic encounters (Baskin, Tierney, Minami, & Wampold, 2003).

Within health psychology, the science of behaviour change has recently undergone a step-change with the development of validated reliable taxonomies of behaviour change techniques (BCTs; Michie et al., 2013; Abraham & Michie, 2008; Michie et al., 2011). BCT taxonomies specify labels and concrete descriptions of psychological techniques that have been included in interventions to change people’s health behaviours. These techniques are the proposed active ingredients of behaviour change interventions; the taxonomies provide a shared language in validated manuals which enable researchers to describe and analyse in detail the contents of interventions, facilitating the precision and communication required to build a cumulative evidence base (Michie & Abraham, 2004; Michie & Johnston, 2012). BCT taxonomies have been used in meta-analytic systematic reviews to identify the active ingredients of interventions and to test the relationship between inclusion of BCTs and intervention success (Michie, Abraham, Whittington, McAteer, & Gupta, 2009; Dombrowski et al., 2012; Taylor, Conner, & Lawton, 2012). Such reviews have generally focused on the content of target interventions rather than controls, although some have described how usual care and/or waiting list controls are more common than active controls and/or have reported the average number of BCTs in controls: 0.8 BCTs in healthy eating and physical activity trials (Michie et al., 2009) and 1.3 in worksite physical activity trials (Taylor et al., 2012). The reason why many reviews do not describe the content of controls may be partly because of poor reporting in the original studies (Dombrowski et al., 2012; Golomb et al., 2010). Indeed, in one review of adherence interventions in HIV, trial authors were asked to complete a checklist so that the reviewers could code the contents of control interventions for meta-analysis (de Bruin, Viechtbauer, Hospers, Schaalma, & Kok, 2009). The reviewers were then able to demonstrate the importance of control conditions: higher quality usual care controls were more effective than lower quality usual care controls (de Bruin et al., 2009) and target interventions which were trialled against higher quality usual care controls had smaller effect sizes than those which were trialled against lower quality usual care controls (de Bruin et al., 2010).

The development of BCT taxonomies not only makes it easier to identify the proposed active ingredients in interventions but also makes it easier (at least conceptually) to isolate active ingredients from contextual components. To maximise internal validity, trials aiming to determine the efficacy of specific BCTs should hold contextual components consistent across target and control interventions. In other words, there should be contextual equivalence across conditions. Although the five contextual domains described above have developed from drug trials, there may be utility in applying them to trials of behavioural interventions. From this perspective, the people delivering the target and control interventions should be the same individuals or have equivalent characteristics. The contact time between the participants and the people delivering each intervention should be the same. The target and control interventions should be similarly credible to participants and should evoke similar outcome expectancies. The interventions should be delivered in the same format or modality and the same environment. The extent of a researcher’s focus on contextual equivalence will depend on the aims of the original study - researchers aiming to test pragmatic effectiveness of complete interventions are unlikely to prioritise contextual equivalence. Nonetheless, previous reviews of behaviour change interventions have not assessed contextual equivalence in this way and doing so may increase our understanding of the effects of behavioural interventions.

Given the potential importance of control interventions and the need for further analyses in this area, we conducted a review of the contents of control interventions in a selected sample of trials to increase physical activity. Our objectives were:

1. To classify and describe control interventions.
2. To compare the contextual equivalence of control and target interventions and test the hypothesis that larger effect sizes will be associated with contextually dissimilar target and control interventions.
3. To compare the BCT contents of control and target interventions and test the hypothesis that larger effect sizes will be associated with having a higher number of unique BCTs in the target intervention.

Meta-analysis was used to examine these issues in RCTs of interventions to increase adherence to physical activity in adults with musculoskeletal pain (Jordan et al., 2010). We chose to focus on physical activity trials in adults with musculoskeletal pain because they are well-suited to exploring our objectives: contextual effects are well-documented in pain and BCTs are commonly used to change physical activity.

**Methods**

***Data collection and coding***

Papers were eligible for inclusion in our review if they were included in the Cochrane review on interventions to improve adherence to exercise in chronic musculoskeletal pain (Jordan et al., 2010). Trials in the Cochrane review were randomised or quasi-randomised trials of interventions to increase adherence to physical activity/exercise in patients with chronic (>3 months) musculoskeletal pain; trials of interventions delivered in in-patient settings were excluded (Jordan et al., 2010). The Cochrane review provided a systematic and well-documented collection of trials addressing an important health psychology topic in a clinical population. Working from a high quality existing review avoided the need to repeat the resource-intensive process of systematically searching the literature and applying unique inclusion/exclusion criteria; this process was not necessary to achieve our objectives.

Full texts of papers included in the Cochrane review were retrieved. Bibliographic and basic methodological details (e.g. n per group, basic description of measures and interventions) were entered into a spread sheet. Outcome data on post-intervention measures of adherence to physical activity (e.g. M, se, SD, OR) were extracted for calculating effect sizes.

The contextual equivalence of the target and control interventions was coded, using a new coding frame based on five contextual domains (Di Blasi et al., 2001) and structural equivalence (Baskin et al., 2003) (Table 1). Brief descriptions of each context domain were written for each target and control intervention. These were then compared to evaluate contextual equivalence. For each domain, studies were awarded 0 if the target and control interventions were equivalent and 1 if they were mismatched. Two researchers worked together to code contextual equivalence; a third researcher checked this coding and discrepancies were resolved through discussion. Fourteen studies (25%) were coded independently by two coders demonstrating reliability in coding (Kappa = 0.83). For a small number of studies it was not possible to describe or code every domain, so proportions are reported below based on the number of studies that were coded for each domain. Each study was awarded a total contextual equivalence score computed as the mean score across all coded domains, ranging from 0 (equivalent across all domains) to 1 (mismatched across all domains).

*[Insert Table 1 Here]*

Two coders (ALFD and FLB) rated each target and control intervention for the presence of each of 93 empirically-derived BCTs, using the coding manual and examples provided in the appendix of the 93-item BCT taxonomy (Michie et al., 2013). The emphasis was on identifying the BCTs used in various interventions rather than only coding what was reported within the constraints of single journal article. Therefore when authors referred readers to other sources for additional details of their interventions (e.g. previous publications, websites, self-help books), these sources were also obtained, reviewed and coded for BCTs. The coders compared coding and collaboratively discussed discrepancies at frequent intervals throughout the coding process and both agreed the final codes. Fourteen studies (25%) were coded independently by the two coders, with acceptable coding reliability (Kappa = 0.84).

The quality of reporting of each study was rated using the CONSORT checklist extension for non-pharmacological interventions (Boutron et al., 2008); the total score was used for analysis (higher score indicates higher quality of reporting).

***Data analysis***

For each trial effect sizes were calculated for the effect of the target intervention(s) on adherence to physical activity. For trials with continuous outcomes, Cohen’s d was calculated as the difference between post-intervention group means divided by the control group standard deviation (Field & Gillett, 2010). For trials reporting the proportion of participants who were adherent, dcox was calculated, where dcox = LN(OR)/1.65 (Sánchez-Meca, Marín-Martínez, & Chacón-Moscoso, 2003).

Trials differed in the type of adherence measure reported. Thirty trials reported a measure of physical activity and 15 reported a measure of attendance at intervention classes or other sessions (three reported both). Fifteen trials did not report the adherence data necessary to enable us to calculate an effect size (e.g. some reported median, some reported neither standard error nor standard deviation). Of these 15 trials, four did report finding no significant between-group differences in adherence but did not report accompanying statistics. To maximise our sample size these studies were assumed to have a very small effect size (d = 0.1). When studies compared more than one target intervention to a control intervention, an effect size was calculated for each target intervention separately. When studies reported adherence measures at more than one time-point, the effect size at the primary endpoint (as designated by the study authors) was used.

To test for the hypothesized moderator effects we conducted meta-regression analysis using random effects models (Field & Gillett, 2010). We grouped studies according to type of adherence measure (attendance or physical activity). For each sub-group, we tested the effects of contextual equivalence and total number of BCTs unique to the target intervention. Quality-of-reporting was also included in the models. Syntax from Field and Gillett (2010) was used to implement this analysis in SPSS.

**Results**

***Basic Meta-Analysis***

A basic fixed effects model of attendance outcomes with no moderators produced a pooled effect size of -0.05 (95% CI = -0.15 to 0.05) with a non-significant Q statistic (χ2(11) = 6.42, p=.844), suggesting homogenous effect sizes among this subgroup of studies. A basic fixed effects model of physical activity outcomes with no moderators produced a pooled effect size of 0.37 (95% CI = 0.31 to 0.43) with a highly significant Q statistic (χ2(25) = 156.76, p=.000), confirming heterogeneity among this subgroup of studies.

***Types of control group***

The 42 studies included in this review tested diverse target and control interventions (Table 2). The most common control interventions were education (12 studies, 30%) and usual care (11 studies, 27%). Education typically took the form of providing participants with written material such as a book or pamphlet but sometimes also involved personal contact in the form of a group lecture or one-to-one session. Usual care was sometimes described in terms of clinical guidelines and could also be referred to as treatment as usual or standard care. Alternative treatments (for example low intensity exercise) and waiting list controls (in which participants had access to the target intervention after a set period) were slightly less popular, used by 9 (22%) and 7 (18%) studies respectively. Only one study (3%) used a sham treatment control.

***Contextual equivalence of control and target interventions***

The contextual equivalence of the control and target interventions was low for all five context domains. In 33% of studies participants in the control intervention had as much contact with the person delivering an intervention as participants in the target intervention. Fewer than half the studies used the same treatment modality for target and control interventions (43%) or were rated as having similarly credible target and control interventions (40%). Just over half the studies used the same or equivalent environments (58%) or practitioners (58%).

Studies which used different types of control group had different levels of contextual equivalence (Table 3). The sham treatment control was equivalent to the target intervention across all 5 context domains, but only one study used a sham treatment control. Alternative treatment controls were frequently equivalent across all five domains, usual care controls were less often equivalent, while (unsurprisingly) waiting list controls were very rarely equivalent. The majority of education controls were equivalent in terms of practitioner characteristics and environment, but not in terms of the other contextual domains.

Table 4 summarises the effect of contextual equivalence on effect size. For physical activity outcomes, two contextual domains predicted effect size after controlling for reporting quality – modality and patient-practitioner relationship. When target and control interventions were delivered in the same modality, target interventions had smaller effect sizes; when target and control interventions involved the same contact time with a practitioner, target interventions had larger effect sizes. There was also a non-significant trend for interventions delivered in the same setting to have larger effect sizes. Contextual equivalence did not predict effect size on class attendance outcomes.

***BCT contents of control and target interventions***

Significantly more BCTs were reported in target interventions (M=11.52, SD = 9.98) than in control interventions (M=4.50, SD = 7.74), t(41) = 4.725, p=.000. Target interventions contained on average 7.64 unique BCTs (SD = 8.97) (i.e. BCTs that were not also included in the control intervention). The five BCTs most commonly used in target interventions were also those that were most commonly used in control interventions: body changes; instruction on how to perform the behaviour; generalisation of target behaviour; graded tasks; and behavioural practice/rehearsal. (For definitions of BCTs see Michie et al., 2013.) Table 5 summarises the effect of BCT content on effect size. For physical activity outcomes, target interventions which contained more unique BCTs were more effective after controlling for reporting quality. For class attendance outcomes, neither the number of unique BCTs nor reporting quality predicted effect size.

**Discussion**

Trials to improve adherence to physical activity in people with musculoskeletal pain use a diverse range of control interventions. Education and usual care controls were the most common while waiting list and alternative treatment controls were each used by approximately one fifth of trials. The only sham treatment control in this review was contextually equivalent to its target intervention across all five context domains. Trials using alternative treatment controls showed greater contextual equivalence than trials using education, usual care, and (unsurprisingly) waiting list controls. The meta-analysis of comparisons on physical activity outcomes showed that some domains of contextual equivalence moderated effect sizes, but not always in the predicted direction. Control interventions typically contained a low number of BCTs and these often overlapped with BCTs in the target interventions. As predicted, having more BCTs unique to the target intervention was associated with larger effect sizes for physical activity outcomes. While this was a small effect, it was independent of reporting quality. There were no moderators of effect size for class attendance outcomes.

Our findings build on previous analyses of BCT content, offering related insights in a new domain, i.e. physical activity interventions in chronic pain. With an average of 4.5 BCTs in the control group trials of adherence to physical activity in chronic pain appear to have more behaviourally active control groups than trials of healthy eating and physical activity interventions (0.8 BCTs) (Michie et al., 2009) and worksite physical activity interventions (1.3 BCTs) (Taylor et al., 2012). Our analysis of physical activity outcomes suggest that having a higher number of BCTs makes target interventions more effective, after taking into account the BCT content of controls and overall reporting quality. Others have found that higher numbers of BCTs are not associated with greater effects on physical activity, for example in obese adults (Dombrowski et al 2012) workers (Taylor et al., 2012) and community-dwelling adults (Michie et al 2009). This disparity might be a consequence of the different populations investigated in these reviews: given the involvement of psychological factors such as fear of pain and activity avoidance in the maintenance musculoskeletal pain (Vlaeyen & Linton 2000) increasing physical activity levels among this group in particular might need more intensive behavioural interventions that incorporate a larger number of specific techniques. Equivalence around modality and patient-practitioner relationships moderated the effect size of interventions. When target and control interventions were delivered in the same modality, interventions had smaller effect sizes. If controlling for contextual processes, modality should thus remain consistent between groups, unless of course modality is a key variable under study. Contradicting our hypothesis, we found that where patient-practitioner relationships were equivalent, there were larger differences between the intervention and control conditions. This could be explained if those trials with equivalent patient-practitioner relationships involved more intensive patient-practitioner relationships than those trials with mismatched relationships. Future reviews in this area could code not only contextual equivalence but also the intensity of contextual components to enable a fuller exploration of how context influences the outcome of behaviour change interventions.

When deciding on control conditions for behaviour change interventions it is important to focus on the primary research question. This question-condition match is critical. If the aim of a study is to test whether a therapist-led group intervention is more effective than the provision of a standardised educational booklet currently used in practice, then contextual equivalence is less important. If, however, the educational booklet condition is intended to control for contextual processes, then our findings suggest it might be inadequate. Educational controls often did control for influences of the practitioner’s characteristics and the environment but very few controlled for the influences of patient-practitioner relationship, patients’ expectations, or treatment modality. Clearly describing the rationale for the design of control conditions will allow readers to draw inferences regarding appropriateness and consider the implications of any contextual differences between target and control interventions.

Others have suggested circumstances in which researchers might prioritise controlling for contextual effects. According to Avins et al. (2012), usual care controls (which do not fully control for context effects) should be chosen in policy-oriented pragmatic trials, while placebo controls (which do control for context effects) should be chosen in explanatory trials. From this perspective, pragmatic trials to inform policy decisions about whether a particular behavioural intervention should be adopted in practice need to prioritise external validity over internal validity: doing otherwise risks testing only a part of the intervention, thus artificially reducing its effectiveness and rejecting it inappropriately. Explanatory trials that aim to identify whether particular BCTs successfully trigger behaviour change should prioritise internal validity over external validity: doing otherwise risks wrongly attributing context effects to the target intervention. Mohr et al (2009) offer a slightly different perspective: they argue that later phase trials (phase III and IV) designed to inform policy decisions should control for threats to internal validity (as stakeholders need to be protected from making type I errors and adopting ineffective or harmful interventions), while early phase trials (phase I and II) designed to develop and pilot-test new interventions should not focus on internal validity as these trials are often small and might fail to detect a clinically meaningful effect (making a type II error) (Mohr et al., 2009).

Limitations in our analysis must be acknowledged. Even when pre-planned, meta-analytic moderator analyses must be interpreted with caution as non-randomised comparisons are being made between trials, which increases risk of confounding (Davey Smith, Egger, & Phillips, 1997). Our meta-analyses of the effects of control group contents on effect size may be confounded by other differences between the original trials. For example, interventions with certain physical therapy techniques might be more likely than those with other physical therapy techniques to have contextually equivalent interventions. Our sub-group of comparisons assessing class attendance outcomes was small and probably under-powered. We explored methodological questions about control group design using trials of physical activity interventions in musculoskeletal pain; similar analyses in other contexts are needed.

Coding the content of control groups was challenging but following-up authors’ references to further details, for example in published protocols, guidelines, and self-help books, helped us to be confident in coding almost all of the trials. Five trials in particular reported very limited descriptions of control interventions, all of which suggested but did not confirm low contextual equivalence and no BCT content. Other reviewers have also found it difficult to code the content of controls. For example, a review of 176 trials reported in major medical journals found that the contents of pill and capsule placebos are rarely described (Golomb et al., 2010). A multiple case study of seven different complex interventions concluded that insufficient details about context are reported in publications even when researchers appreciate the significant impact of contextual features on trial conduct and outcomes (Wells, Williams, Treweek, Coyle, & Taylor, 2012). Similarly, a review of 82 antidepressant drug trials found that reporting of contextual components was unsystematic and insufficient (Hughes, Gabbay, Funnell, & Dowrick, 2012). Systematic reporting of the contents of control conditions would help future meta-analyses to take this into account.

In conclusion, trials to increase adherence to physical activity in musculoskeletal pain use a diverse range of control interventions, some of which include their own BCTs and some of which control for multiple contextual factors. The contents of control conditions can influence the effect size shown by the target intervention and should be considered carefully in trial design and systematic reviews.

References

Abraham, C. & Michie, S. (2008). A taxonomy of behavior change techniques used in interventions. *Health Psychology, 27,* 379-387.

Ahn, H. & Wampold, B. E. (2001). Where oh where are the specific ingredients? A meta-analysis of component studies in counseling and psychotherapy. *Journal of Counseling Psychology, 48,* 251-7.

\*Åsenlöf, P., Denison, E., & Lindberg, P. (1-9-2005). Individually Tailored Treatment Targeting Activity, Motor Behavior, and Cognition Reduces Pain-Related Disability: A Randomized Controlled Trial in Patients With Musculoskeletal Pain. The Journal of Pain, 6, 588-603.

Avins, A., Cherkin, D., Sherman, K., Goldberg, H., & Pressman, A. (2012). Should we reconsider the routine use of placebo controls in clinical research? *Trials, 13,* 44.

Bandura, A. (1997). *Self-Efficacy. The exercise of control*. New York: W.H. Freeman and Company.

\*Barlow, J. H., Turner, A. P., & Wright, C. C. (2000). A randomized controlled study of the Arthritis Self-Management Programme in the UK. *Health Education Research, 15,* 665-680.

Baskin, T. W., Tierney, S. C., Minami, T., & Wampold, B. E. (2003). Establishing specificity in psychotherapy: a meta-analysis of structural equivalence of placebo controls. *Journal of Consulting and Clinical Psychology, 71,* 973-979.

\*Basler, H. D., Bertalanffy, H., Quint, S., Wilke, A., & Wolf, U. (2007). TTM-based counselling in physiotherapy does not contribute to an increase of adherence to activity recommendations in older adults with chronic low back pain - A randomised controlled trial. *European Journal of Pain, 11,* 31.

Benedetti, F. & Amanzio, M. (2011). The placebo response: How words and rituals change the patient's brain. *Patient Education and Counseling, 84,* 413-419.

\*Bernaards, C. M., Ariëns, G. A. M., Knol, D. L., & Hildebrandt, V. H. (2007). The effectiveness of a work style intervention and a lifestyle physical activity intervention on the recovery from neck and upper limb symptoms in computer workers. *Pain* 132, 142-153.

\*Blixen, C. E., Bramstedt, K. A., Hammel, J. P., Hammel, J. P., & Tilley, B. C. (2004). A pilot study of health education via a nurse-run telephone self-management programme for elderly people with osteoarthritis . *Journal of Telemedicine and Telecare, 10,* 44-49.

Boutron, I., Moher, D., Altman, D. G., Schulz, K.F., & Revaud, P. for the CONSORT Group. (2008). Extending the CONSORT Statement to randomized trials of nonpharmacologic treatment: explanation and elaboration. *Annals of Internal Medicine, 148,* 295-309.

\*Carr, J. L., Klaber Moffett, J. A., Howarth, E., Richmond, S. J., Torgerson, D. J., Jackson, D. A. et al. (2005). A randomized trial comparing a group exercise programme for back pain patients with individual physiotherapy in a severely deprived area. *Disability and Rehabilitation, 27,* 929-937.

\*Cohen, M. J., Heinrich, R. L., Naliboff, B. D., Collins, G. A., & Bonebakker, A. D. (1983). Group outpatient physical and behavioral therapy for chronic low back pain. *Journal of Clinical Psychology, 39,* 326-333.

Crow, R., Gage, H., Hampson, S., Hart, J., Kimber, A., & Thomas, H. (1999). The role of expectancies in the placebo effect and their use in the delivery of health care: a systematic review. *Health Technology Assessment, 3*.

Davey Smith, G., Egger, M., & Phillips, A. N. (1997). Meta-analysis: Beyond the grand mean? *British Medical Journal, 315*.

de Bruin, M., Viechtbauer, W., Hospers, H. J., Schaalma, H. P., & Kok, G. (2009). Standard care quality determines treatment outcomes in control groups of HAART-adherence intervention studies: implications for the interpretation and comparison of intervention effects. *Health Psychology, 28,* 668-674.

de Bruin, M., Viechtbauer, W., Schaalma, H. P., Kok, G., Abraham, C., & Hospers, H. J. (2010). Standard care impact on effects of highly active antiretroviral therapy adherence interventions. *Archives of Internal Medicine, 170,* 240-250.

Di Blasi, Z., Harkness, E., Ernst, E., Georgiou, A., & Kleijnen, J. (2001). Influence of context effects on health outcomes: a systematic review. *Lancet, 357,* 757-762.

Dombrowski, S. U., Sniehotta, F. F., Avenell, A., Johnston, M., MacLennan, G., & Ara+¦jo-Soares, V. (2012). Identifying active ingredients in complex behavioural interventions for obese adults with obesity-related co-morbidities or additional risk factors for co-morbidities: a systematic review. *Health Psychology Review, 6,* 7-32.

Drahota, A., Ward, D., Mackenzie, H., Stores, R., Higgins, B., Gal, D. et al. (2012). Sensory environment on health-related outcomes of hospital patients (Review). *Cochrane Database of Systematic Reviews, 3,* Art. No.: CD005315. DOI: 10.1002/14651858.CD005315.pub2.

\*Ersek, M., Turner, J. A., Cain, K. C., & Kemp, C. A. (15-8-2008). Results of a randomized controlled trial to examine the efficacy of a chronic pain self-management group for older adults [ISRCTN11899548]. *Pain,* 138, 29-40.

\*Ettinger, W. H., Jr, Burns, R., & Messier, S. P. (1997). A randomized trial comparing aerobic exercise and resistance exercise with a health education program in older adults with knee osteoarthritis: The fitness arthritis and seniors trial (fast). *Journal of the American Medical Association, 277,* 25-31.

\*Ferreira, M. L., Ferreira, P. H., Latimer, J., Herbert, R. D., Hodges, P. W., Jennings, M. D. et al. (1-9-2007). Comparison of general exercise, motor control exercise and spinal manipulative therapy for chronic low back pain: A randomized trial. *Pain,* 131, 31-37.

Field, A. P. & Gillett, R. (2010). How to do a meta-analysis. *British Journal of Mathematical and Statistical Psychology, 63,* 665-694.

\*Fransen, M., Nairn, L., Winstanley, J., Lam, P., & Edmonds, J. (2007). Physical activity for osteoarthritis management: A randomized controlled clinical trial evaluating hydrotherapy or Tai Chi classes. *Arthritis Care & Research, 57,* 407-414.

Freedland, K. E., Mohr, D. C., Davidson, K. W., & Schwartz, J. E. (2011). Usual and Unusual Care: Existing Practice Control Groups in Randomized Controlled Trials of Behavioral Interventions. *Psychosomatic Medicine, 73,* 323-335.

\*Friedrich, M., Cermak, T., & Maderbacher, P. (1996). The Effect of Brochure Use Versus Therapist Teaching on Patients Performing Therapeutic Exercise and on Changes in Impairment Status. *Physical Therapy, 76,* 1082-1088.

\*Friedrich, M., Gittler, G., Halberstadt, Y., Cermak, T., & Heiller, I. (1998). Combined exercise and motivation program: Effect on the compliance and level of disability of patients with chronic low back pain: A randomized controlled trial. *Archives of Physical Medicine and Rehabilitation, 79,* 475-487.

\*Fries, J. F., Carey, C., & McShane, D. J. (1997). Patient education in arthritis: randomized controlled trial of a mail-delivered program. *The Journal of Rheumatology, 24,* 1378-1383.

Golomb, B. A., Erickson, L. C., Koperski, S., Sack, D., Enkin, M., & Howick, J. (2010). What's in placebos: who knows? Analysis of randomized, controlled trials. *Annals of Internal Medicine, 153,* 532-535.

\*Halbert, J., Crotty, M., Weller, D., Ahern, M., & Silagy, C. (2001). Primary care-based physical activity programs: effectiveness in sedentary older patients with osteoarthritis symptoms. *Arthritis Care & Research, 45,* 228-234.

\*Härkäpää, K., Mellin, G., Järvikoski, A., & Hurri, H. (1990). A controlled study on the outcome of inpatient and outpatient treatment of low back pain. Part III. Long-term follow-up of pain, disability, and compliance. *Scandinavian Journal of Rehabilitation Medicine, 22,* 181-188.

\*Huang, M. H., Lin, Y. S., Lee, C. L., & Yang, R. C. (2005). Use of ultrasound to increase effectiveness of isokinetic exercise for knee osteoarthritis. *Archives of Physical Medicine and Rehabilitation, 86*, 1545-51.

\*Huang, M. H., Lin, Y. S., Yang, R. C., & Lee, C. L. (2003). A comparison of various therapeutic exercises on the functional status of patients with knee osteoarthritis. *Seminars in Arthritis and Rheumatism, 32,* 398-406.

Hughes, J., Gabbay, M., Funnell, E., & Dowrick, C. (2012). Exploratory review of placebo characteristics reported in randomised placebo controlled antidepressant drug trials. *Pharmacopsychiatry, 45,* 20-27.

\*Hughes, S. L., Seymour, R. B., Campbell, R., Pollak, N., Huber, G., & Sharma, L. (2004). Impact of the Fit and Strong Intervention on Older Adults With Osteoarthritis. *The Gerontologist, 44,* 217-228.

\*Hurley, M. V., Walsh, N. E., Mitchell, H. L., Pimm, T. J., Patel, A., Williamson, E. et al. (2007). Clinical effectiveness of a rehabilitation program integrating exercise, self-management, and active coping strategies for chronic knee pain: A cluster randomized trial. *Arthritis Care & Research, 57,* 1211-19.

\*Jensen, I. B., Bergstrom, G., Ljungquist, T., Bodin, L., & Nygren, +. L. (1-3-2001). A randomized controlled component analysis of a behavioral medicine rehabilitation program for chronic spinal pain: are the effects dependent on gender? *Pain, 91,* 65-78.

Jordan, J. L., Holden, M. A., Mason, E. E. J., & Foster, N. E. (2010). Interventions to improve adherence to exercise for chronic musculoskeletal pain in adults. *Cochrane Database of Systematic Reviews,* Art. No.: CD005956. DOI: 10.1002/14651858.CD005956.pub2.

Kaptchuk, T. J., Kelley, J. M., Conboy, L. A., Davis, R. B., Kerr, C. E., Jacobson, E. E. et al. (2008). Components of placebo effect: randomised controlled trial in patients with irritable bowel syndrome. *British Medical Journal, 336,* 999-1003.

Kirsch, I. (1997). Response expectancy theory and application: A decennial review. *Appl Prev Psychol, 6,* 69-79.

Kirsch, I. (2005). Placebo psychotherapy: Synonym or oxymoron? *Journal of Clinical Psychology, 61,* 791-803.

\*Koumantakis, G. A., Watson, P. J., & Oldham, J. A. (1-6-2005). Supplementation of general endurance exercise with stabilisation training versus general exercise only: Physiological and functional outcomes of a randomised controlled trial of patients with recurrent low back pain. *Clinical Biomechanics, 20,* 474-482.

\*Lorig, K., Lubeck, D., Kraines, R. G., Seleznick, M., & Holman, H. R. (1985). Outcomes of self-help education for patients with arthritis. *Arthritis & Rheumatism, 28,* 680-685.

Luborsky, L., Rosenthal, R., Diquer, L., Andrusyna, T. P., Berman, J. S., Levitt, J. T. et al. (2002). The Dodo bird verdict is alive and well – mostly. *Clinical Psychology: Science and Practice, 9,* 2-12.

\*Luszczynska, A., Gregajtys, A., & Abraham, C. (2006). Effects of a self-efficacy intervention on initiation of recommended exercises in patients with spondylosis. *Journal of Aging and Physical Activity, 15,* 26-40.

\*Mangione, K. K., McCully, K., Gloviak, A., Lefebvre, I., Hofmann, M., & Craik, R. (1999). The Effects of High-Intensity and Low-Intensity Cycle Ergometry in Older Adults With Knee Osteoarthritis. *The Journals of Gerontology Series A: Biological Sciences and Medical Sciences, 54,* M184-M190.

\*McCarthy, C. J., Mills, P. M., Pullen, R., Roberts, C., Silman, A., & Oldham, J. A. (2004). Supplementing a home exercise programme with a class-based exercise programme is more effective than home exercise alone in the treatment of knee osteoarthritis. *Rheumatology, 43,* 880-6.

Michie, S., Abraham, C., Whittington, C., McAteer, J., & Gupta, S. (2009). Effective techniques in healthy eating and physical activity interventions: a meta-regression. *Health Psychology, 28,* 690-701.

Michie, S. & Abraham, C. (2004). Interventions to change health behaviours: evidence-based or evidence-inspired? *Psychology and Health, 19,* 29-49.

Michie, S., Ashford, S., Sniehotta, F. F., Dombrowski, S. U., Bishop, A., & French, D. P. (2011). A refined taxonomy of behaviour change techniques to help people change their physical activity and healthy eating behaviours: The CALO-RE taxonomy. *Psychology & Health, 26,* 1479-1498.

Michie, S. & Johnston, M. (2012). Theories and techniques of behaviour change: Developing a cumulative science of behaviour change. *Health Psychology Review, 6,* 1-6.

Michie, S., Richardson, M., Johnston, M., Abraham, C., Francis, J., Hardeman, W. et al. (2013). The Behavior Change Technique Taxonomy (v1) of 93 hierarchically clustered techniques: Building an international consensus for the reporting of behavior change interventions. *Ann.Behav.Med.,* 1-15.

\*Mikesky, A. E., Mazzuca, S. A., Brandt, K. D., Perkins, S. M., Damush, T., & Lane, K. A. (2006). Effects of strength training on the incidence and progression of knee osteoarthritis. *Arthritis Care & Research, 55,* 690-699.

\*Minor, M. A., Hewett, J. E., Webel, R. R., Anderson, S. K., & Kay, D. R. (1989). Efficacy of physical conditioning exercise in patients with rheumatoid arthritis and osteoarthritis. *Arthritis & Rheumatism, 32,* 1396-1405.

Mohr, D. C., Spring, B., Freedland, K. E., Beckner, V., Arean, P., Hollon, S. D. et al. (2009). The selection and design of control conditions for randomized controlled trials of psychological interventions. *Psychotherapy and Psychosomatics, 78,* 275-284.

\*Nour, K., Laforest, S., Gauvin, L., & Gignac, M. (2006). Behavior change following a self-management intervention for housebound older adults with arthritis: an experimental study. *International Journal of Behavioral Nutrition and Physical Activity, 3,* 12.

\*Petrella, R. J. & Bartha, C. (2000). Home based exercise therapy for older patients with knee osteoarthritis: a randomized clinical trial. *The Journal of Rheumatology, 27,* 2215-2221.

Sánchez-Meca, J., Marín-Martínez, F., & Chacón-Moscoso, S. (2003). Effect-size indices for dichotomized outcomes in meta-analysis. *Psychological Methods, 8,* 448-467.

\*Schoo, A. M. M., Morris, M. E., & Bui, Q. M. (2005). The effects of mode of exercise instruction on compliance with a home exercise program in older adults with osteoarthritis. *Physiotherapy, 91,* 79-86.

\*Sherman, K. J., Cherkin, D. C., Erro, J., Miglioretti, D. L., & Deyo, R. A. (2005). Comparing yoga, exercise, and a self-care book for chronic low back pain. A randomized, controlled trial. *Annals of Internal Medicine, 143,* 849-856.

\*Smeets, R., Vlaeyen, J., Hidding, A., Kester, A., van der Heijden, G., van Geel, A. et al. (2006). Active rehabilitation for chronic low back pain: Cognitive-behavioral, physical, or both? First direct post-treatment results from a randomized controlled trial [ISRCTN22714229]. *BMC Musculoskeletal Disorders, 7,* 5.

\*Söderlund, A. & Lindberg, P. (2001). Cognitive behavioural components in physiotherapy management of chronic whiplash associated disorders (WAD) - a randomised group study. *Physiotherapy Theory and Practice, 17,* 229-238.

\*Song, R., Lee, E. O., Lam, P., & Bae, S. C. (2003). Effects of tai chi exercise on pain, balance, muscle strength, and perceived difficulties in physical functioning in older women with osteoarthritis: a randomized clinical trial. *The Journal of Rheumatology, 30,* 2039-2044.

\*Soukup, M. G., Glomsröd, B., Lönn, J. H., Bö, K., & Larsen, S. (1999). The Effect of a Mensendieck Exercise Program as Secondary Prophylaxis for Recurrent Low Back Pain: A Randomized, Controlled Trial With 12-Month Follow-up. *Spine, 24*.

\*Taimela, S., Takala, E. P., Asklöf, T., Seppälä, K., & Parviainen, S. (2000). Active Treatment of Chronic Neck Pain: A Prospective Randomized Intervention. *Spine, 25*.

\*Talbot, L. A., Gaines, J. M., Huynh, T. N., & Metter, E. J. (2003). A Home-Based Pedometer-Driven Walking Program to Increase Physical Activity in Older Adults with Osteoarthritis of the Knee: A Preliminary Study. *Journal of the American Geriatrics Society, 51,* 387-392.

Taylor, N., Conner, M., & Lawton, R. (2012). The impact of theory on the effectiveness of worksite physical activity interventions: a meta-analysis and meta-regression. *Health Psychology Review, 6,* 33-73.

\*Veenhof, C., Köke, A. J. A., Dekker, J., Oostendorp, R. A., Bijlsma, J. W. J., van Tulder, M. W. et al. (2006). Effectiveness of behavioral graded activity in patients with osteoarthritis of the hip and/or knee: A randomized clinical trial. *Arthritis Care & Research, 55,* 925-934.

\*Viljanen, M., Malmivaara, A., Uitti, J., Rinne, M., Palmroos, P., & Laippala, P. (2003). Effectiveness of dynamic muscle training, relaxation training, or ordinary activity for chronic neck pain: randomised controlled trial. *British Medical Journal, 327*.

Vlaeyen, J. W. S. & Linton, S. J. (2000). Fear-avoidance and its consequences in chronic musculoskeletal pain: a state of the art. *Pain, 85,* 317-332.

Wampold, B. E., Mondin, G. W., Moody, M., Stich, F., Benson, K., & Ahn, H. (1997). A meta-analysis of outcome studies comparing bona fide psychotherapies: empirically, "all must have prizes". *Psychological Bulletin, 122,* 203-215.

Wells, M., Williams, B., Treweek, S., Coyle, J., & Taylor, J. (2012). Intervention description is not enough: evidence from an in-depth multiple case study on the untold role and impact of context in randomised controlled trials of seven complex interventions. *Trials, 13,* 95.

\*Yip, Y. B., Sit, J. W., Fung, K. K. Y., Wong, D. Y. S., Chong, S. Y. C., Chung, L. H. et al. (1-1-2007). Impact of an arthritis self-management programme with an added exercise component for osteoarthritic knee sufferers on improving pain, functional outcomes, and use of health care services: An experimental study. Patient Education and Counseling 65, 113-121.

\*Ylinen, J., Takala, E., Nykänen, M., Mälkiä, E., Pohjolainen, T., Karppi, S. L. et al. (2003). Active neck muscle training in the treatment of chronic neck pain in women: A randomized controlled trial. *Journal of the American Medical Association, 289,* 2509-2516.

Table 1. Coding frame for contextual components.

|  |  |  |
| --- | --- | --- |
| Context Domain | Definition | Notes |
| Practitioner Characteristics | Characteristics of person(s) delivering the interventions. | Consider status, expertise, qualifications and experience related to the intervention the practitioner(s) delivers. |
| Patient-Practitioner Relationship | Total duration of contact time between participant and person(s) delivering the interventions. | Include all contact related to intervention-delivery. Do not include contact time between investigators and participants where it relates only to trial procedures (e.g. data collection, consent). |
| Intervention Credibility | Overall perceived credibility or face validity of the interventions.  | Used as a proxy for participants’ expectations. If participants are only informed about their intervention or are blinded to allocation, code as “equivalent”. |
| Superficial Treatment Characteristics | Treatment modality of the interventions. | Common modalities include face-to-face, group, individual, web-based, telephone, paper-based. One intervention may use multiple modalities. |
| Environment | Physical setting in which the interventions are delivered. | Common settings include hospital, clinic, rehabilitation centre, participant’s home, community centre.  |

Table 2. Description of control and target interventions by study.

|  |  |  |
| --- | --- | --- |
| Study | Target Intervention | Control Intervention |
| Asenlof (2005) | Individually tailored behavioural medicine intervention (n=38) | Usual care: physical exercise therapy, designed to be equivalent to best standard practice based on clinical guidelines (n=43) |
| Barlow (2000) | Arthritis self-management programme (n=311) | 4-month waiting list (n=233) |
| Basler (2007) | Physiotherapy plus brief behavioural counseling (n=75) | Physiotherapy plus sham ultrasound (n=72) |
| Bernaards (2007) | RSI@Work: Work style intervention (n=152) or Work style and physical activity (n=156) | Usual care following Dutch guidelines for occupational health management (n=158) |
| Blixen (2004)  | Self-management programme including mailed documents, instructional audio tape, and telephone educational support calls in addition to usual care (n=16) | Usual care from rheumatologist (n=16) |
| Carr (2005) | Back to Fitness programme: a physiotherapy-led exercise class incorporating cognitive behavioural principles (n=118) | Usual care: individual physiotherapy as is normally conducted in the UK (n=119)  |
| Cohen (1983) | Behavioural therapy (n=13) | Physical therapy (n=12) |
| Ersek (2008) | Pain self-management training group (n=133) | Educational book: The Chronic Pain Workbook or Managing Your Pain Before It Manages You (n=123) |
| Ettinger (1997) | Aerobic exercise training - walking (n=144) or Resistance exercise training (n=146) | Health education programme designed to provide attention, social interaction and education (n=149) |
| Ferreira (2007) | Motor control exercise with CBT principles (n=74) or Spinal manipulative therapy (n=77) | General exercise, based on Back to Fitness programme with CBT principles (n=80) |
| Fransen (2007)  | Tai Chi (n=56) or Hydrotherapy (n=55) | 12 week waiting list (n=41) |
| Friedrich (1996) | Brochure plus physical-therapist instructed exercise (n=47) | Brochure-instructed exercise (n=40) |
| Friedrich (1998) | Combined exercise and motivation programme (n=44) | Standard exercise programme (n=49) |
| Fries (1997)  | Mail-delivered version of the arthritis self-management program (n=375) | Waiting list (n=434) |
| Halbert (2001) | Individualized physical activity advice (n=37) | Usual care and a pamphlet on good nutrition for older adults (n=32) |
| Harkapaa (1990) | In-patient physiotherapist led group-based back treatment programme (n=157) or Out-patient physiotherapist led group-based back treatment programme (n=159) | Written and oral instructions on back exercises from physiatrist (n=160) |
| Huang (2003) | Isokinetic muscle-strengthening (n=33), or isotonic muscle-strengthening (n=33), or isometric muscle-strengthening (n=33) | Described as "control group", no further details available (n=33) |
| Huang (2005)  | Isokinetic muscle-strengthening (n=30) or Isotonic muscle-strengthening (n=30) or Isometric muscle-strengthening (n=30) | Described as "control group", no further details available (n=30) |
| Hughes (2004) | Fit and Strong, facility-based multiple component training program (n=68) | "Waiting list" given self-management book (Arthritis Helpbook), list of local exercise classes, printed self-care advice (n=43) |
| Hurley (2007) | Usual primary care plus rehabilitation programme including exercise, education, self-management, health beliefs delivered on an individual basis (n=120) or in groups (n=107) | Usual primary care as determined by the patient's primary care physician (n=111) |
| Jensen (2001) | Behaviour oriented physical therapy (n=54) or Cognitive behavioural therapy (n=49) or Behavioural medicine rehabilitation - physical therapy + CBT (n=63) | Treatment as usual, described as unlikely to include comprehensive rehabilitation (n=48) |
| Koumantakis (2005) | Written advice (Back Book) plus specific muscle stabilisation-enhanced general exercise (n=24) | Written advice (Back Book) plus general exercise (n=21) |
| Lorig (1985) | Arthritis self-management program (n=129) | 4 month waiting list (n=61) |
| Luszczynska (2006)  | Education session based around rehabilitation exercise leaflet plus mastery and verbal persuasion intervention | Education session based around rehabilitation exercise leaflet  |
| Mangione (1999) | High intensity exercise (n=19) | Low intensity exercise (n=20) |
| McCarthy (2004) | Home exercise programme and class-based exercise programme (n=84) | Home exercise programme (n=62) |
| Mikesky (2006) | Strength training plus video and booklets (n=113) | Range of motion exercises plus booklets (n=108) |
| Minor (1989) | Aerobic exercise program (n=36) or Aerobic aquatics program (n=47) | Non-aerobic range-of-motion exercise (n=32) |
| Nour (2006) | Home-based self-management programme - I'm taking charge of my arthritis (n=65) | One year waiting list (n=48) |
| Petrella (2000) | Home based progressive exercise program plus treatment with the nonsteroidal medication oxaprozin (n=91) | Treatment with the nonsteroidal medication oxaprozin (n=88) |
| Schoo (2005) | Home exercise brochure plus audiotape (n=30) or plus videotape (n=30) | Home exercise brochure (n=30) |
| Sherman (2005)  | Yoga classes (n=36) or Exercise classes including education (n=33) | Education book - The Back Pain Help Book (n=30) |
| Smeets (2006) | Active physical treatment (n=53) or Cognitive behavioural therapy (n=58) or Active physical treatment + cognitive behavioural therapy (n=61) | 10 week waiting list followed by regular individual rehabilitation |
| Söderlund (2001) | Individual physiotherapy with integrated cognitive behavioural components (n=16) | Individual physiotherapy - standardised usual care (n=16) |
| Song (2003) | Tai Chi (n=22) | 12 week waiting list (n=21) |
| Soukup (1999) | Mesendieck programme, including education and exercise (n=17) | Written and oral information about the Mesendieck program (n=9) |
| Taimela (2000)  | Active group - proprioceptive exercises, relaxation and behavioural support, and lecture and written information (n=25) or Home group - home exercises instruction and progress diary, and lecture and written information (n=25) | Lecture and written information recommending exercises (n=26) |
| Talbot (2003)  | Arthritis self-management programme plus walking programme (n=17) | Arthritis self-management programme (n=17) |
| Veenhof (2006)  | Behavioural graded activity programme (n=90) | Usual care following Dutch guidelines (n=102) |
| Viljanen (2003) | Dynamic muscle training (n=135) or Relaxation training (n=128) | Ordinary activity - participants instructed not to change their physical activity during the trial (n=130) |
| Yip (2007) | Arthritis self-management programme plus exercise (n=88) | Usual care - routine orthopaedic treatment (n=94)  |
| Ylinen (2003) | Physiotherapy and multimodal rehabilitation plus either endurance training (n=60) or strength training (n=60) | 1 year waiting list, plus education to exercise (n=60) |

Table 3. Frequency and percentage of contextual equivalence by type of control group.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Control | Practitioner Characteristics | Patient-Practitioner Relationship | Intervention Credibility | Modality | Environment |
| Alternative treatment | 7 (88%) | 7 (78%) | 6 (67%) | 6 (67%) | 7 (88%) |
| Education | 7 (88%) | 1 (8%) | 3 (25%) | 5 (42%) | 7 (70%) |
| Usual Care | 6 (55%) | 3 (27%) | 4 (36%) | 5 (46%) | 5 (50%) |
| Waiting List | 1 (14%) | 1 (14%) | 1 (14%) | 0 | 1 (14%) |
| Sham treatment | 1 (100%) | 1 (100%) | 1 (100%) | 1 (100%) | 1 (100%) |
| Fisher’s Exact | 8.84\* | 13.56\*\* | 6.81 | 8.88\* | 9.46\* |

\*p<.05 \*\*p<.01

Table 4. Moderating effect of contextual equivalence on effect sizes.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | 95% CI |  |  |
| Moderator | Beta | Lower | Upper | t(df) | p |
|  |  |  |  |  |  |
| **Physical Activity Outcomes a** |  |  |  |  |  |
| Reporting Quality | .023 | .000 | .046 | 1.973 (39) | .056 |
| Modality | -.344 | -.648 | -.040 | -2.258 (39) | .030 |
| Patient-Practitioner Relationship | .400 | .154 | .646 | 3.248 (39) | .002 |
| Intervention Credibility | -.164 | -.534 | .206 | -0.883 (39) | .383 |
| Environment | .157 | -.020 | .335 | 1.767 (39) | .085 |
| Practitioner Characteristics | .041 | -.098 | .180 | 0.590 (39) | .559 |
| **Class Attendance Outcomes b** |  |  |  |  |  |
| Reporting Quality | -.001 | -.083 | .082 | -.019 (3) | .986 |
| Modality | -.075 | -.424 | .274 | -.446 (3) | .686 |
| Patient-Practitioner Relationship | -.302 | -1.200 | 0.596 | -.696 (3) | .536 |
| Intervention Credibility | .431 | -.627 | 1.490 | .843 (3) | .461 |

aBased on 47 comparisons reported in 21 studies, total N = 11203

bBased on 9 comparisons reported in 6 studies, total N = 1362. There was 100% equivalence on practitioner characteristics and environment for comparisons on class attendance outcomes.

Table 5. Moderating effect of BCT content on effect sizes.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | 95% CI |  |  |
| Moderator | Beta | Lower | Upper | t(df) | p |
|  |  |  |  |  |  |
| **Physical Activity Outcomes a** |  |  |  |  |  |
| Reporting Quality | .029 | .012 | .046 | 3.476 (48) | .001 |
| Number of BCTs unique to target intervention | .008 | .001 | .015 | 2.234 (48) | .030 |
| **Class Attendance Outcomes b** |  |  |  |  |  |
| Reporting Quality | .031 | -.019 | .081 | 1.236 (9) | .248 |
| Number of BCTs unique to target intervention | -.010 | -.037 | .017 | -.735 (9) | .481 |

aBased on 52 comparisons reported in 24 studies, total N = 11695.

bBased on 13 comparisons reported in 8 studies, total N = 1581.

1. We resist the labels “non-specific” and “placebo”, and instead we prefer the term “context effects”, as these components and their effects are well-theorised and are not illusory (as sometimes “placebo” is taken to mean). For example, the effects of patients’ expectations are explained by expectancy theory (Kirsch, 1997) and social cognitive theory (Bandura, 1997). [↑](#footnote-ref-1)