Duke GLOBAL HEALTH INSTITUTE | Research Design & Analysis Core

Supplemental Material 1: CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial [12]

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	
	2b	Specific objectives or research questions for pilot trial	
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	
Participants	4a	Eligibility criteria for participants	
	4b	Settings and locations where the data were collected	
	4c	How participants were identified and consented	
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	
Outcomes	6a	Completely defined pre-specified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	
Sample size	7a	Rationale for numbers in the pilot trial	
	7b	When applicable, explanation of any interim analyses and stopping guidelines	
Randomization:			
Sequence generation	8a	Method used to generate the random allocation sequence	
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	
Results			

Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	
	13b	For each group, losses and exclusions after randomisation, together with reasons	
Recruitment	14a	Dates defining the periods of recruitment and follow-up	
	14b	Why the pilot trial ended or was stopped	
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	
Numbers analyzed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomized group	
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomized group	
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	
	19a	If relevant, other important unintended consequences	
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	
Generalizability	21	Generalizability (applicability) of pilot trial methods and findings to future definitive trial and other studies	
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	
Protocol	24	Where the pilot trial protocol can be accessed, if available	
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	
	26	Ethical approval or approval by research review committee, confirmed with reference number	

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Supplemental Material 2: Example Abstracts from *Pilot and Feasibility Studies* Journal

Assessing the feasibility of evaluating and delivering a physical activity intervention for pre-school children: a pilot randomized controlled trial [15]

Published: *18 February 2016*

Sally E. Barber, Cath Jackson, Catherine Hewitt, Hannah R. Ainsworth, Hannah Buckley, Shaheen Akhtar, Daniel D. Bingham, Ash C. Routen, Carolyn Summerbell, Gerry Richardson, Helen J. Moore, Kate E. Pickett, Claire O'Malley, Shirley Brierley and John Wright

ABSTRACT

Background

Few evidence-based physical activity interventions for pre-school children are available. This two-armed pilot cluster randomized controlled trial aimed to evaluate the feasibility of conducting a full-scale trial and of delivering an outdoor physical activity intervention for pre-school children.

Methods

School was the unit of randomization, and follow-up occurred at 10 and 52 weeks. Trial feasibility was assessed by recruitment, retention and completion rates of primary (daily moderate-to-vigorous physical activity (MVPA)) and secondary (anthropometric, quality of life, self-efficacy) outcomes. Potential effectiveness was assessed for the primary outcome using a linear regression model comparing MVPA between trial arms adjusting for clustering by school. Feasibility of delivering the intervention was assessed by intervention fidelity and attendance. Semi-structured interviews with parents, intervention facilitators, and head teachers explored acceptability and capability to deliver the intervention as well as acceptability of the study design.

Results

Recruitment rates were 37 % of schools (n = 10 schools) and 48 % of pre-school children (n = 164 children). Retention of children to the trial at 52 weeks was 83.5 %. Thirty-nine percent of children had valid primary outcome accelerometer data at baseline and 52 weeks. Response rates for secondary outcome measures ranged from 52 to 88 % at 10 weeks and 59 to 80 % at 52 weeks. The mean difference in daily MVPA between trial arms at 52 weeks was 0.4, 95 % CI 16.3 to 17.0; p = 0.96. Fidelity of intervention implementation was 81 %. Intervention attendance was higher (82 %) during the summer initiation phase compared to autumn/spring initiation (50 %). Parents, facilitators and head teachers found the intervention acceptable and beneficial.

Conclusions

Recruitment and retention rates suggest a trial in this outdoor setting with this population was feasible but is weather sensitive. However, strategies to increase accelerometer wear-time would need to be implemented for reliable primary outcome data to be obtained. There was high implementation fidelity by facilitators, and the intervention was seen as acceptable and deliverable. However, attendance was low and preliminary data showed no evidence of intervention effectiveness. A revised intervention, building on the successful elements of this pilot alongside adapting implementation strategies to improve attendance, should therefore be considered.

Trial registration

Trial registry name and number: Current Controlled Trials, ISRCTN54165860. Date of registration: 4 September 2012.

Keywords: Physical activity intervention Pre-school children Pilot randomized controlled trial Process evaluation Deprivation Ethnicity

Western medical acupuncture in a group setting for knee osteoarthritis: results of a pilot randomized controlled trial [16]

Published: *16 February 2016*

Adrian White, Liz Tough, Vicky Eyre, Jane Vickery, Anthea Asprey, Cath Quinn, Fiona Warren, Colin Pritchard, Nadine E. Foster, Rod S. Taylor, Martin Underwood and Paul Dieppe

ABSTRACT

Background

Evidence suggests acupuncture may be effective for treating the symptoms of knee osteoarthritis. Offering this in a group setting may offer cost savings. The aim of this study was to establish the feasibility of a definitive trial to assess the clinical and cost-effectiveness of Western medical acupuncture given in groups, or given individually, for adults with severe knee pain attributable to osteoarthritis.

Methods

A pilot randomized controlled trial (RCT) was conducted. Participants were recruited from seven general practices in Plymouth, Devon. Acupuncture was provided, at a dosage that increased up to and including electroacupuncture if no pain relief was reported, by one experienced acupuncturist in a community clinic. Potentially eligible adults aged at least 45 years with knee osteoarthritis were identified from practice registers, screened and randomized to either: (1) standardised advice and exercise booklet alone ('standard'); (2) booklet plus group acupuncture ('group'); and (3) booklet plus individual acupuncture ('individual'). Both acupuncture arms received up to ten treatments over 12 weeks.

Recruitment, retention and data completion rates were recorded, and participants completed questionnaires on acceptability. We collected pain, stiffness and function data (using the Western Ontario McMaster Universities Osteoarthritis Index; WOMAC) and general health (EQ-5D) and economic measures at baseline and 14 weeks post-randomization.

Results

We screened 149 people and randomized 60 (40 %), 20 per arm. The overall 14 week follow-up rate was 77 %, but only 70 % in the 'standard' group; 4.1 % of data points were missing. The study was acceptable to participants. Changes in WOMAC pain score (intention to treat complete case analysis) from baseline to 14 week follow-up were: 'standard', 0.4 (95 % confidence interval (CI) −1.4, 2.2, $n = 14$); 'group' −3.2 (95 % CI −5.1, −1.4, $n = 17$); 'individual' −2.4 (95 % CI −4.1, −0.7, $n = 15$).

Conclusions

A definitive three-arm trial is feasible. Further follow-up reminders, minimum data collection and incentives should be considered to improve participant retention in the follow-up processes in the standardised advice and exercise booklet arm.

Trial registration

ISRCTN05305406

Keywords: Primary health care Knee osteoarthritis Randomised controlled trial Acupuncture Healthcare delivery Pilot project

Prescribed computer games in addition to occlusion versus standard occlusion treatment for childhood amblyopia: a pilot randomized controlled trial [17]

Published: *11 June 2015*

Vijay K. Tailor, Selina Glaze, Payal Khandelwal, Alison Davis, Gillian G. W. Adams, Wen Xing, Catey Bunce and Annegret Dahlmann-Noor

ABSTRACT

Background

Amblyopia ("lazy eye") is the commonest vision deficit in children. If not fully corrected by glasses, amblyopia is treated by patching or blurring the better-seeing eye. Compliance with patching is often poor. Computer-based activities are increasingly topical, both as an adjunct to standard treatment and as a platform for novel treatments. Acceptability by families has not been explored, and feasibility of a randomized controlled trial (RCT) using computer games in terms of recruitment and treatment acceptability is uncertain.

Methods

We carried out a pilot RCT to test whether computer-based activities are acceptable and accessible to families and to test trial methods such as recruitment and retention rates, randomization, trial-specific data collection tools and analysis. The trial had three arms: standard near activity advice, Eye Five, a package developed for children with amblyopia, and an off-the-shelf handheld games console with pre-installed games. We enrolled 60 children age 3–8 years with moderate or severe amblyopia after completion of optical treatment.

Results

This trial was registered as UKCRN-ID 11074. Pre-screening of 3600 medical notes identified 189 potentially eligible children, of whom 60 remained eligible after optical treatment, and were enrolled between April 2012 and March 2013. One participant was randomized twice and withdrawn from the study. Of the 58 remaining, 37 were boys. The mean (SD) age was 4.6 (1.7) years. Thirty-seven had moderate and 21 severe amblyopia. Three participants were withdrawn at week 6, and in total, four were lost to follow-up at week 12. Most children and parents/carers found the study procedures, i.e. occlusion treatment, usage of the allocated near activity and completion of a study diary, easy. The prescribed cumulative dose of near activity was 84 h at 12 weeks. Reported near activity usage numbers were close to prescribed numbers in moderate amblyopes (94 % of prescribed) but markedly less in severe amblyopes (64 %). Reported occlusion usage at 12 weeks was 90 % of prescribed dose for moderate and 33 % for severe amblyopes.

Conclusions

Computer-based games and activities appear acceptable to families as part of their child's amblyopia treatment. Trial methods were appropriate and accepted by families.

Keywords: Amblyopia Child Clinical trial