



NCCHTA

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Final Protocol

1. Project Title

The Effectiveness and Cost-effectiveness of Weight Management Schemes for the Under 5's

2. TAR team and project 'lead'

TAR team: Peninsula Technology Assessment Group (PenTAG)

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3. Plain English Summary

This project will review evidence for the effectiveness of schemes to manage the weight of children under five years old. The evidence will come from well designed research studies conducted either in the UK or comparable countries, either delivered by health services, the education sector or commercially. The evidence will be brought together to find out which schemes produce the best results. We will also look to see which schemes give the best value for money.

4. Decision problem

4.1. Purpose

The purpose of this systematic review is to evaluate evidence for the effectiveness and cost-effectiveness of weight management schemes for the under 5's (before children reach the age of formal schooling). This is necessary due to the escalating problem of childhood obesity ($\geq 95^{\text{th}}$ UK National BMI percentile). The National Institute of Health and Clinical Excellence (NICE) recommends that tailored clinical interventions should be considered for children with a BMI at or above the 91st centile, depending on the needs of the individual child and family, and that an assessment of comorbidity should be considered for children with a BMI at or above the 98th centile.¹ The prevalence of childhood obesity in England has risen between 1995 and 2007 for children aged 2-15, from 11% to 17% for boys and 12% to 16% for girls.² Overall, in the UK, 10% of preschool children are obese,³ with a quarter of children aged 2-5 being either overweight ($\geq 85^{\text{th}} < 95^{\text{th}}$ UK National BMI percentile) or obese.^{4;5}

The effects of early childhood obesity include an increased risk of obesity in later childhood⁶ and later life⁷ with an associated increased likelihood of developing heart disease, diabetes or cancer.⁸ There is therefore a window of opportunity to intervene in the lives of pre-school children to prevent later morbidity and premature mortality,⁹ and to meet the NICE Guidelines' target of halting the annual rise in obesity in children under 11 by 2010.¹ The Government has set itself a new ambition:

“of being the first major country to reverse the rising tide of obesity and overweight in the population by ensuring that all individuals are able to maintain a healthy weight. Our initial focus is on children: by 2020 we will have reduced the proportion of overweight and obese children to 2000 levels”.¹⁰

4.2. Inclusion criteria

Criteria	Specification	Notes
Population	Under 5 year olds	Distinguish 0-2s and 2-<5s where possible
Intervention	Weight management schemes/interventions designed to maintain appropriate weight and /or achieve weight loss and/or manage weight gain	Whether delivered by the health sector, education sector or commercially
Comparator	Normal practice	
Outcomes	Measures of weight and weight maintenance	Clinical effectiveness studies must include at least one measure of adiposity
	Quality of life Health outcomes Objective measures of health behaviour Cost and cost-effectiveness	not self-reported outcomes
Setting	Settings with relevance to the UK	OECD countries
Study design	Clinical effectiveness: Systematic reviews of RCTs, RCTs, other controlled trials	
	Cost-effectiveness: as above and additionally, decision model analyses, or analyses of person-level cost and effectiveness data alongside observational studies. Cost-effectiveness analyses, cost-utility analyses, cost-benefit analyses and cost-consequence analyses. UK cost analyses.	
Search dates	1990 onwards	
Length of follow-up	At least 12 weeks/three months	Depending on description
Language	English language only	

4.3. Key factors to be considered

As data permit, we will produce an evidence synthesis to compare the effectiveness of different schemes to help children under five years old, lose weight, maintain weight or manage weight gain. This will include:

- A systematic review of clinical effectiveness studies of individual schemes
- Analysis of direct comparisons between studies where data permit
- In the absence of direct comparisons, the use of the indirect comparison approach
- Within included studies; a consideration of the barriers and facilitators to weight management
- A systematic review of cost-effectiveness studies of individual schemes
- The identification of recommendations for future primary research

5. Search Strategy

Refer to Appendix 1 for the draft search strategy for MEDLINE.

The search strategy will comprise the following main elements:

- Searching of electronic bibliographic databases
- Internet searches
- Scrutiny of references of included studies
- Contacting experts in the field

Databases will include:

MEDLINE, EMBASE, MEDLINE(R) In-Process & Other Non-Indexed Citations, ISI Science Citation Index, Cochrane Database of Systematic Reviews, CENTRAL, NHS EED, DARE, HTA (NHS-CRD); ISI Proceedings, Current Controlled Trials, NIHR CRN CC, Clinical Trials.gov, PsychLIT, EPPI-Centre.

6. Methods for synthesis of evidence of clinical effectiveness

The assessment report will include a systematic review of the evidence for the clinical effectiveness of schemes for the weight management of the under fives. The review will be undertaken following the general principles published by the NHS Centre for Reviews and Dissemination.¹¹

6.4. Study Selection Criteria and procedures

6.4.1. Types of studies to be included

For the reviews of clinical effectiveness, systematic reviews of RCTs, RCTs and other controlled designs, will be included. Studies will only be included if they are relevant to the inclusion criteria.

6.4.2. Types of studies to be excluded

- Uncontrolled studies
- Animal models
- Narrative reviews, editorials, opinions
- Non English language papers

- Reports published as meeting abstracts only, or where insufficient methodological details are reported to allow critical appraisal of study quality.

6.4.3. Study selection process:

Based on the above inclusion/exclusion criteria, papers will be selected for review, independently by three reviewers, from the titles and abstracts generated by the search strategy. Discrepancies will be resolved by discussion. Retrieved papers will again be selected against the inclusion criteria by the same independent process.

Data extraction strategy

Data will be extracted from included studies by one reviewer using a standardised data extraction form and checked by another reviewer. Discrepancies will be resolved by discussion, with the involvement of a third reviewer if necessary.

Quality assessment strategy

The quality of the clinical effectiveness studies will be assessed for internal and external validity according to criteria suggested by the updated NHS CRD Report No.4, according to study type.¹¹

Methods of analysis/synthesis

All included studies will be given a summary description.

It is to be expected that much heterogeneity will exist between the studies, including varying types of interventions, outcomes and definitions of obesity; in which case careful consideration will be given to the extent of the heterogeneity and its likely effect on validity if data were pooled, before meta-analysis is considered to be appropriate. Where pooling of data is not applicable, data will be tabulated and discussed in a narrative review.

Where suitable, meta-analysis of RCTs will be employed to estimate a summary measure of effect on relevant outcomes based on intention to treat analyses. If meta-analysis is conducted it will be carried out using fixed or random effects models, using StatsDirect or STATA software. Heterogeneity will be explored through consideration of the study populations, methods and interventions and, in statistical terms, by the χ^2 test for

homogeneity and the I^2 statistic and methods such as meta-regression. If direct comparisons are not possible between studies indirect comparisons will be made as data permit.

7. Methods for synthesis of evidence of cost-effectiveness

7.1. Search strategy

The range of sources searched will be the same as those for clinical effectiveness but also include NHS EED.

7.1.1. Study selection criteria and procedures

The inclusion and exclusion criteria for the systematic review of economic evaluations will be identical to those for the systematic review of clinical effectiveness, except:

Non-randomised studies will be included (e.g. decision model based analyses, or analyses of person-level cost and effectiveness data alongside observational studies.)

Full cost-effectiveness analyses, cost-utility analyses, cost-benefit analyses and cost consequence analyses will be included. Stand alone UK cost analyses will also be sought and appraised.

Based on the above inclusion/exclusion criteria, study selection will be made independently by two reviewers. Discrepancies will be resolved by discussion, with involvement of third reviewer when necessary.

7.2. Study quality assessment

The methodological quality of the economic evaluations will be assessed according to internationally accepted criteria such as the CHEC list questions developed by Evers et al.¹² Any studies based on decision models will also be assessed against the ISPOR guidelines for good practice in decision analytic modelling.¹³

7.3. Data extraction strategy

Data will be extracted by one researcher into two summary tables: one to describe the study design of each economic evaluation and the other to describe the main results.

In study design table: author and year; model type or trial based; study design (e.g. CEA, CUA or cost-analysis); service setting/country; study population; comparators; research

question; perspective, time horizon, and discounting; main costs included; main outcomes included; sensitivity analyses conducted; and other notable design features.

The Results table will reflect the outcomes used in the studies. The original authors' conclusions will be noted, and also any issues they raise concerning the generalisability of results. Finally the reviewers' comments on study quality and generalisability of their results will be recorded.

7.4. Synthesis of extracted evidence

Narrative synthesis, supported by the data extraction tables, will be used to summarise the evidence base.

8. Expertise in this TAR team

Name	Institution	Expertise
Mrs Mary Bond	PenTAG, Peninsula Medical School, Universities of Exeter and Plymouth	Systematic reviewing and project management
Dr Katrina Wyatt	Peninsula Medical School, Universities of Exeter and Plymouth	Systematic reviewing and child health
Ms Jenny Lloyd	Peninsula Medical School, Universities of Exeter and Plymouth	Systematic reviewing and child health
Mrs Karen Welch	Karen Welch Information Consultancy	Information science
Dr Rod Taylor	PenTAG, Peninsula Medical School, Universities of Exeter and Plymouth	Systematic reviewing and meta-analysis

In addition to the research team, we will be receiving expert advice from Prof. John Reilly, Professor of Paediatric Energy Metabolism at the University of Glasgow.

TAR Centre

This project is being conducted by The Peninsula Technology Assessment Group (PenTAG), which is part of the Institute of Health Service Research at the Peninsula Medical School. PenTAG was established in 2000 and carries out independent Health Technology Assessments for the UK HTA Programme and other local and national decision-makers including NICE. The group is multi-disciplinary and draws on individuals' backgrounds in

public health, health services research, computing and decision analysis, systematic reviewing, statistics and health economics. The Peninsula Medical School is a school within the Universities of Plymouth and Exeter. The Institute of Health Service Research is made up of discrete but methodologically related research groups, among which Health Technology Assessment is a strong and recurring theme.

Recent publications from this project team include:

Bond M, Pitt M, Akoh J, Moxham T, Hoyle M, Anderson R. The effectiveness and cost-effectiveness of methods of storing donated kidneys from deceased donors: a systematic review and economic model. *Health Technol Assess*. 2009. In press.

Bond M, Mealing S, Anderson R, Dean J, Stein K, **Taylor RS**. Is combined resynchronisation and implantable defibrillator therapy a cost effective option for left ventricular dysfunction? *Int J Cardiol*.2008

Bond M, Mealing S, Anderson R, Elston J, Weiner G, **Taylor RS**, Hoyle M, Liu Z, Price A, Stein K. The effectiveness and cost-effectiveness of cochlear implants for severe to profound deafness in children and adults: a systematic review and economic model. *Health Technol Assess*. 2008 in press

Fox M, Mealing S, Anderson R, Dean J, Stein K, Price A, **Taylor RS**. The clinical effectiveness and cost-effectiveness of cardiac resynchronisation (biventricular pacing) for heart failure: systematic review and economic model. *Health Technol Assess* 2007;**11**(47).

Garside R, Stein K, **Wyatt K**, Round A. Microwave and thermal balloon ablation for heavy menstrual bleeding: a systematic review. *BJOG: An International Journal of Obstetrics and Gynaecology* 2005; 112: 12-23

Tierney S, **Wyatt K**. What works for adolescents with Anorexia Nervosa? A systematic review of psychosocial interventions. *Eat Weight Disord*. 2005 10(2):66-75

Team members' contribution

Name	Job title	Contribution
Mary Bond	Research Fellow in Health Technology Assessment	Providing overall project management. Writing the protocol. Assessing abstracts and titles and papers for inclusion and exclusion in both systematic reviews. Leading the clinical and cost-effectiveness systematic reviews. Leading the writing and editing the report.
Katrina Wyatt	Senior Research Fellow in Child Health	Assessing abstracts and titles and papers for inclusion and exclusion in the effectiveness systematic review. Contributing to the clinical effectiveness systematic review. Contributing to the writing and editing the report.
Jenny Lloyd	Research Fellow in Child Health	Assessing abstracts and titles and papers for inclusion and exclusion. Contributing to the clinical effectiveness systematic review. Contributing to the writing and editing the report.
Karen Welch	Information Scientist	Writing and running the search strategies for clinical and cost-effectiveness.
Rod Taylor	Associate Professor	Assessing abstracts and titles and papers for inclusion and exclusion in the cost-effectiveness systematic review. Overseeing all the statistical analysis. Contributing to the writing and editing the report. Overall director of the project and guarantor of the report.

9. Competing interests of authors

None

10. Timetable

This is a Short Report, which means that the final report should be handed in 12 weeks from signing-off the protocol. However, this project may be extended if the size of the searches, or other unforeseen circumstances, means that this short time frame needs extending.

11. Appendices

11.1. Medline search strategy Effectiveness of Weight Management Schemes for the Under 5's

The Effectiveness and Cost Effectiveness of Weight Management in the Under 5's

Medline Draft Strategy for Clinical Effectiveness. 1950-current (also includes restriction to 1990-current also)
26/01/09

Summary of search approach:

Search statement 9 represents all the obesity terms (= or/1-8)
Search statement 14 represents the age group (= or/10-13)
Search statement 61 represents the interventions (=or/15-60)
Search statement 88 represents the trial restrictions (-or/62-87)
Combination of obesity, age, intervention and trial restrictions = line 89
Restriction to English language and human = line 90
Restriction of search from 1990-current – line 91

Summary of Numbers of results in the search strategy:

954 results linking the 4 sets (all years 1950-current)
771 restricting to English Language and Human (all years 1950-current)
681 further restriction 1990-current

- 1 exp Obesity/ (87578)
- 2 exp weight gain/ (15486)
- 3 exp weight loss/ (17639)
- 4 Overweight/ (2747)
- 5 (overweight or over weight or overeate* or over eat* or overfeed* or over feed*).ti,ab. (19013)
- 6 (weight gain or weight loss).ti,ab. (57800)
- 7 ((bmi or body mass index) adj5 (gain or loss or change)).ti,ab. (2057)
- 8 obes*.ti,ab. (93177)
- 9 or/1-8 (182010)
- 10 Child, Preschool/ (609134)
- 11 Infant/ (522071)
- 12 (baby or babies or toddler* or infant* or newborn* or neonat* or preschool* or pre school* playschool* or playgroup* or kindergarten* or kindergarden*).ti,ab. (422006)
- 13 infant newborn/ (411242)
- 14 or/10-13 (1200448)
- 15 family therapy/ (6516)
- 16 Health Knowledge, Attitudes, Practice/ (41563)
- 17 Diet Therapy/ (8620)
- 18 Obesity/dh [Diet Therapy] (4041)
- 19 Diet, Fat-Restricted/ (1938)
- 20 Diet, Reducing/ (7673)
- 21 diet therapy/ (8620)
- 22 (diet or diets or dieting).ti,ab. (167724)
- 23 Professional-Family Relations/ (9066)
- 24 health behavior/ (19098)
- 25 parenting/px (2970)

- 26 caregivers/px (7597)
- 27 Schools, Nursery/st [Standards] (32)
- 28 Nutrition Policy/ (3619)
- 29 Preventive Health Services/ (8406)
- 30 obesity/pc (6207)
- 31 child care/st (229)
- 32 Nurseries/st [Standards] (39)
- 33 Community Health Planning/ or Community Health Services/ (25699)
- 34 Counseling/ (21829)
- 35 (low calorie or calorie control* or healthy eating).ti,ab. (2570)
- 36 (diet* adj (modific* or therapy or intervention* or strateg* or program* or management or scheme*)).ti,ab. (7665)
- 37 exercise/ (44627)
- 38 exercise therapy/ (17728)
- 39 "Play and Playthings"/ (5284)
- 40 (aerobic* or physical therap* or physical activit* or physical inactivity).ti,ab. (73848)
- 41 (fitness adj (class or regime* or program* or group* or session* or scheme*)).ti,ab. (514)
- 42 sedentary behavio?r reduction.ti,ab. (1)
- 43 reduc* sedentary behavio?r.ti,ab. (26)
- 44 dance.mp. and (therapy or activity or class* or program* or group* or session* or scheme*).ti,ab. [mp=title, original title, abstract, name of substance word, subject heading word] (585)
- 45 ((playschool or communit* or toddler* or kindergarten) adj2 (program* or sheme*)).ti,ab. (4139)
- 46 (family* scheme* or families scheme* parent* scheme* or carer* scheme* or guardian* scheme*).ti,ab. (2)
- 47 (family* intervention* or families intervention* parent* intervention* or carer* intervention* or guardian* intervention*).ti,ab. (657)
- 48 (parent adj2 (behavio?r or involvement or control* or attitude* or education*)).ti,ab. (1309)
- 49 (group adj (therapy or intervention* or program* or strateg* or management or scheme*)).ti,ab. (4523)
- 50 (community adj (therapy or intervention* or program* or strateg* or management or scheme*)).ti,ab. (1838)
- 51 (health polic* or preschool polic* or playschool polic* or food polic* or nutrition polic*).ti,ab. (9453)
- 52 primary prevention/ (10129)
- 53 (preventive measure* or peventative measure*).ti,ab. (10112)
- 54 (individual* adj (therapy or intervention* or program* or strateg* or management)).ti,ab. (2610)
- 55 (exercise and (therapy or activity or class* or program* or group* or session* or scheme*)).ti,ab. (61306)
- 56 (population adj (therapy or intervention* or program* or strateg* or management or scheme*)).ti,ab. (1020)
- 57 Health Education/ (43710)
- 58 health promotion/ (34176)
- 59 secondary prevention/ (19)
- 60 health scheme*.ti,ab. (146)
- 61 or/15-60 (551893)
- 62 Randomized Controlled Trials as Topic/ or Clinical Trials as Topic/ or Random Allocation/ (242254)
- 63 Controlled Clinical Trial/ (77815)
- 64 controlled clinical trial.pt. (77815)
- 65 randomized controlled trial.pt. (260879)
- 66 Random Allocation/ (62415)

- 67 double blind method/ or single blind method/ (109892)
- 68 ((singl* or doubl* or trebl* or tripl*) adj (blind* or mask*)).ti,ab. (95193)
- 69 research design/ (54026)
- 70 ((random* or control*) adj5 (trial* or stud*)).ti,ab. (331722)
- 71 (randomised or randomized).ti,ab. (219179)
- 72 Comparative Study/ (1403101)
- 73 Evaluation Studies as Topic/ (117391)
- 74 (matched communities or matched populations).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (102)
- 75 (control* adj (trial* or stud* or evaluation*)).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (461891)
- 76 (comparison group* or control* group*).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (187738)
- 77 Matched-Pair Analysis/ (3089)
- 78 matched pair*.ti,ab. (3698)
- 79 (nonrandomi?ed or non randomi?ed or pseudo randomi?ed).ti,ab. (8494)
- 80 Meta-Analysis/ (19604)
- 81 meta analy*.ti,ab. (22393)
- 82 "Outcome Assessment (Health Care)"/ (31054)
- 83 outcome stud*.ti,ab. (4007)
- 84 Intervention Studies/ (3873)
- 85 Prospective Studies/ (248566)
- 86 follow up studies/ (370664)
- 87 exp clinical trial/ (552777)
- 88 or/62-87 (2728384)
- 89 9 and 14 and 61 and 88 (954)**
- 90 limit 89 to (english language and humans) (771)**
- 91 limit 90 to yr="1990 - 2009" (681)**

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