D.23 Exercise

Item	Details
Key issue in the scope	The role of exercise in maintaining health.
Review question in the scope	What is the effectiveness of programmes of exercise in the management of cystic fibrosis?
Review question for the protocol	What is the effectiveness of programmes of exercise in the management of cystic fibrosis?
Objective	Exercise has been identified as potential therapeutic and prognostic tool which has been linked to many improved outcomes in people with CF. While physical training is part of the typical care offered to a person with CF, many people are thought to refrain from physical activity due to fatigue and shortness of breath. Further, a 2012 Cochrane review suggested that the benefits of exercise may be influenced by the "type of training programme and the inclusion of aerobic and anaerobic training". The aim of this review is to evaluate whether specific programmes of physical exercise lead to improved outcomes and benefits for people with CF.
Language	English
Study design	• Systematic reviews of RCTs

Item	Details
	• RCTs (Only RCTs with N>10 will be included. RCTs with n = 10 or n < 10 and analysed in an included Cochrane systematic review will be included). • Conference abstracts of RCTs (Only if RCTs unavailable and the quality assessment of abstracts will conducted based on the available information and if necessary the authors of abstracts will be contacted). • Comparative cohort studies (only if RCTs unavailable or limited data to inform decision making)
Population and directness	Children, young people and adults with CF, diagnosed clinically and by sweat test or genetic testing. Population size and indirectness: • Studies with N < 10 will not be included. • Studies with indirect population will not be considered.
Stratified, subgroup and adjusted analyses	Stratified analysis: • Supervised vs unsupervised training In the event of heterogeneity, the following subgroups that will be analysed separately: • Severity • Gender (male versus female) • Age (≤17 years versus ≥18 years) • Duration of exercise programme (short versus long) In the presence of heterogeneity, sensitivity analysis will conducted including and excluding studies with a high risk of bias.
Intervention	Any clearly defined (supervised and unsupervised) physical exercise programme: • Aerobic exercise programmes • Strength resistance training (anaerobic exercise programmes) • High intensity interval training • Habitual physical activity • Inspiratory muscle training (> 80%) • Any combination of the above
Comparison	• No defined exercise programme • A different defined exercise programme – for example different activities or different duration or intensity of the same activity
Outcomes	• Lung function tests - forced expiratory volume in one second (FEV1) per cent predicted (change from baseline will be favoured over absolute data) • Forced vital capacity (FVC) per cent predicted (change from baseline will be favoured over absolute data) • VO2 (change from baseline will be favoured over absolute data) • Time to next exacerbation • Preference for training programme • Quality of life (CFQ-R, CF-QOL) • Body composition (change in BMI or weight) (≥ 3 months follow-up) • Adverse events, i.e. fractures • Note: change from baseline will be prioritised over absolute values
Importance of outcomes	Critical outcomes for decision making: • Lung function (FEV1) • Quality of life (CFQ-R, CF-QOL) • Time to next exacerbation
Setting	Any healthcare setting where NHS care is delivered (primary, secondary, tertiary or community).

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Search strategy	Sources to be searched: Medline, Medline In-Process, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, Cochrane Database of Abstracts of Reviews of Effectiveness, Health Technology Database, Embase Limits (e.g. date, study design): Apply standard exclusions and English language filters. Limit to RCTs and systematic reviews in the first instance but download all study designs. Supplementary search techniques: No supplementary search techniques will be used. See appendix E.18 for full search strategies
Review strategy	Appraisal of methodological quality: • The methodological quality of each study will be assessed using an appropriate checklist as per NICE guidelines manual (The Cochrane Risk of Bias tool for RCTs and the Newcastle and Ottawa scale for observational studies). • The quality of the evidence will be assessed by GRADE for each outcome according to the process described in the NICE guidelines manual (2014). Synthesis of data: • Meta-analysis will be conducted where appropriate. • Final and change scores will be pooled and if any study reports both, change scores will be used in preference over final scores. • If studies only report p-values from parametric analyses, and 95% CIs cannot be calculated from other data provided, this information will be plotted in GRADE tables, but evidence may be downgraded. • If studies only report p-values from non-parametric analyses, this information will be plotted in GRADE tables without downgrading the evidence, as imprecision cannot be assessed for non-parametric analyses. Minimal important differences (MIDs): • FEV1: 5 percentage points • FVC: GRADE default • VO2 max: GRADE default • Time to next exacerbation: any change will be considered clinically significant • BMI or weight: GRADE default • Quality of life: CF-QOL = 5; CFQ-R = 8.5 • Preference: GRADE default • Adverse events = GRADE default • Major adverse events leading to discontinuation of treatment: any change will be considered clinically significant Default MIDs: 0.8 and 1.25 for dichotomous outcomes; 0.5 times SD for continuous outcomes. • Review process: • A list of excluded studies will be provided following weeding. • Evidence tables and an evidence profile will be used to summarise the evidence.
Equalities	• Psychological and behavioural issues are more likely in people with a lower socioeconomic status • Gender- outcomes are worse for women although there is no evidence that this is a consequence of difference in care • Geographical issues – care is given through specialist centres and this may be a problem if a person with CF is living in an isolated location.
Notes/additional information	Physical training for cystic fibrosis (Cochrane Review), Bradley 2012 http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD002768.pub2/pdf

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	A randomized controlled trial of a 3-year home exercise program in cystic fibrosis: http://www.jpeds.com/article/S0022-3476(00)12109-2/pdf Individualised unsupervised exercise training in adults with cystic fibrosis: a 1 year randomised controlled trial: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1746905/pdf/v059p01074.pdf Exercise programs for children with cystic fibrosis: A systematic review of randomized controlled trials: http://informahealthcare.com/doi/abs/10.3109/09638280902991842 The evidence regarding exercise training in the management of cystic fibrosis: a systematic review http://europepmc.org/articles/PMC2845226;jsessionid=RQBVQg74VEBAkBcBVUMH.11