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Hub ConDuCT-II	Host University University of Bristol
Supervisor Deborah Caldwell d.m.caldwell@bristol.ac.uk	Co-supervisors Rona Campbell; Sara Brookes
Is the project clinical or non clinical? Non-clinical	
Title of PhD project: Feasibility and acceptability of developing core outcome sets in effectiveness trials for universal school-based public health interventions	

Background: In Public Health (PH) it is acknowledged that interventions are unlikely to 'work' the same way widely. However, one consequence of this for PH trial design has been the use of discipline-specific, ad hoc or unvalidated outcome measures. This results in inconsistency of outcomes across trials of a similar intervention[1], which in turn prevents meaningful evidence synthesis due to heterogeneity of outcomes and high risk of bias. Since a systematic review should be conducted before the design of a new PH trial[2], this heterogeneity of outcomes is perpetuated with ongoing consequences for methodological quality and trial design. Core outcome sets (COS) are an agreed minimum set of outcomes to be measured and reported in all effectiveness trials. However, the focus has been on clinical, therapeutic interventions and only a few COS have been developed for PH interventions[3]. Established methods for developing COS may not be optimal for PH interventions due to important methodological challenges: PH interventions have multiple active components, they are delivered to diverse participants who are typically healthy and outcomes are longer-term than clinical trials. Compared to clinical settings there is a wider range of settings in which the same intervention can be delivered and a wider range of stakeholders (e.g. GPs, Local Authorities, social workers, health visitors, teachers, pupils, parents and PH consultants). Interventions designed to target the same health issue may be delivered to an individual, a group or be environmental/ structural. These factors are likely to cause greater diversity of relevant outcomes and gaining consensus for a minimum outcome set may be more difficult due to the competing interests. Conversely, relevant stakeholders in any particular PH setting (such as schools) are likely to remain the same regardless of disease area, hence we may have the opportunity to answer multiple questions in one consensus process (e.g. a core set for all school health interventions with a series of add-on modules for different disease areas within that setting). This would enable better efficiency of limited resources and time, and improve the design of future PH trials.

What studentship will encompass*:* This PhD will consider school-based PH interventions for mental health, obesity and sexual health/ relationships to answer the following methodological questions: (i) Can consensus of a PH COS be achieved across diverse stakeholder groups (ii) Is a modular COS system feasible and acceptable; can it be developed within one COS process? Are core outcomes generic to all preventive interventions in a given setting?

The PhD will follow the stages of COS development recommended by COMET[2]: (i) Phase 1- identification of a 'long list' of potential outcomes through systematic reviews of PH school-based interventions in the three disease areas (including trials, population-level surveys and local authority school surveys; (ii) Phase 2 - prioritization of outcomes using a Delphi survey; this will include 3 questionnaires or 'rounds', asking participants to rate the importance of different outcomes to be measured in future trials, average scores are fed back to participants in subsequent rounds, and; (iii) Phase 3 - consensus meeting to finalize core items and disease-specific modules. The degree of consensus achieved will be explored in each round by examination of: the percentage of discordant items (where there is disagreement between stakeholder groups); differences in scores between stakeholder groups; variability in scores across stakeholders.[3] Participant acceptability of the process and of a modular COS will be sought via qualitative interviews with a purposeful sample of stakeholders (approximately 20).

***Detail of supervision*:** The supervisors have expertise in PH trials, systematic reviews and statistics. Dr Caldwell will support the systematic review aspects. Prof. Campbell is co-director of DECIPHer (centre for the Development and Evaluation of Complex Interventions for Public Health Improvement)[4] which has a strong track record of evaluating PH interventions in RCTS. Dr. Brookes is a medical statistician, joint lead of the ConDuCT-II Hub outcomes theme and the HTMR Working Group on Outcomes in trials; she has contributed substantially to development of COSs.

References: **(1)** *Shepperd et al.* PLoS Medicine 2009 (**2**) *Craig et al* BMJ 2008 **(3)** http://www.comet-initiative.org **(4)** Brookes *et al*. *Trials,* 2016. **(5)** http://decipher.uk.net/

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Supplementary information

1. Describe the alignment of the project with the HTMR Network strategy
   Promote high quality collaborative methodological research relevant to trials, both across Hubs and with other groups, UK-wide and internationally. The project is a collaboration between supervisors affiliated with HTMR, Cochrane and DECIPHer.
   Encourage the implementation of the most effective and appropriate methods in clinical trials. The COMET initiative has published guidance for developing COS that will be followed in this project. Public Health (PH) research is conducted across a wide range of professions and there is a pressing need to standardise the outcomes evaluated in all trials to avoid unnecessary duplication of effort and expenditure.
   Work with external stakeholders, in particular to agree on shared priorities for research and guidance. The PhD requires the student to engage with stakeholders from across public health –NICE, GPs, School Nurses, Local Authorities, Education Professionals and researchers. Children and their guardians will also be involved in the work; engaging with the public maximises the opportunity for knowledge translation.
   Strengthen research training and capacity in methodology in the UK. The PhD student will have access to the courses outlined below. This work will also enable cross-dissemination of methods between DECIPHer, ConDuCT and Cochrane.

2. Does this project align with the work of a HTMR Working Group; if so, which?
   The Outcomes working group.

3. Describe how this project aligns with the host Hub strategy
   ConDuCT-II considers methodologies to improve the design and conduct of difficult and complex randomized controlled trials; trials of public health interventions fit well with this. One theme within ConDuCT-II is 'Outcomes' which includes a focus on the development of core outcome sets.

4. Detail of any Project specific training offered in the studentship
   DECIPHer courses on the (i) development of, and (ii) evaluation of public health interventions. SSCM run a successful short course programme including 'Introduction to Randomised Controlled Trials', 'Systematic Reviews and Meta-analysis', 'Introduction to Statistics'. Courses will be dependent on the successful applicant's training needs and interests. The project will fully engage with systematic review producers, such as the Cochrane Collaboration Public Health review group. Visits to the Cochrane group could form part of this PhD.

5. Are there any prerequisite qualifications or experience for this studentship?
   Candidates for an MRC-funded studentship must meet residence eligibility and hold qualifications in a relevant subject at the level of, or equivalent to, a good honours degree from a UK academic institution (see methodology website for more details- www.methodologyhubs.mrc.ac.uk).

   For this project: MSc in a Health Science or health-related subject, such as Public Health, Epidemiology, Psychology, Medical Statistics. First degree in a science or social science subject, min. 2:1.