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NEWS AND VIEWS

Nutrition Bulletin

Medical Research Council Hot Topic workshop report: Planning a UK Nutrition and Healthy Life Expectancy Trial

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Abstract

There is a drive in the UK to harness findings from novel fundamental and efficacy nutritional research and, through inter-disciplinary and multi-agency collaborations, to improve eating behaviour for the benefit of population health. This report summarises the progress made during the Medical Research Council-funded Hot Topic workshop on the planning for a potential UK-wide nutrition primary prevention randomised controlled trial with incident disease as the study endpoint: the UK *Nutrition and Healthy Life Expectancy (NuLifE)* Trial. Through two workshops, along with online discussions and a systematic evidence synthesis, over 40 experts from a range of disciplines came together over 6 months. The workshop reached a consensus and delivered a three-stage plan with the ultimate ambitious aim of providing effective eating behaviour change strategies to address the growing inequalities in the UK and contribute to both a reduced risk of prevalent diet-related chronic disease and an increase in healthy life expectancy.

KEYWORDS
ageing, eating behaviour, life expectancy, nutrition, randomised controlled trial

INTRODUCTION

The Medical Research Council (MRC)-National Institute for Health Research (NIHR) *Review of Nutrition and Human Health Research* 2017 report highlighted the need to 'pull-through' a strong basic science nutrition portfolio in the UK into a population health and economic benefit (MRC, 2017). The UK Nutrition Research Partnership awards, funded by the MRC in partnership with the Biotechnology and Biological Sciences Research Council and NIHR, were established to take forward this agenda, including supporting 'Hot Topic' workshops that would provide novel and robust insights into human nutrition and enhance interdisciplinary collaborations.

The overall objective for this workshop was to progress ideas and planning for a potential UK-wide nutrition primary prevention randomised controlled trial (RCT) with incident disease as the study endpoint: the *UK Nutrition and Healthy Life Expectancy (NuLifE)* Trial.

This workshop was organised by the principal investigator Anne-Marie Minihane (AMM), along with an early career researcher, co-principal investigator, Jennifer Carter (JC). A working group of key collaborators that helped with the planning of the workshop were John Mathers (JM), Susan Jebb (SJ), Susan

Fairweather-Tait (SF) and Naveed Sattar (NS), with Amy Jennings (AJ) conducting a systematic review to inform the *NuLifE* trial design. The workshops were attended by 42 participants from 19 organisations with expertise in nutritional epidemiology, nutritional science, behavioural science, ageing, public health, chronic disease pathology, weight loss, nutrigenomics, health inequalities, clinical trial design and delivery, business strategy, public policy, health economics and digital technology (Appendix A). Senior researchers were encouraged to identify early career researchers to attend.

RATIONALE FOR THE WORKSHOP

Although beginning to plateau, life expectancy (LE) in the UK has increased 2–3 years every decade for the last century and currently stands at 79 and 83 years for males and females. However, healthy life expectancy (HALE) is not increasing at the same rate, with an increased rate for HALE:LE of 0.8 (ONS, 2018). This is in effect creating one additional year of ill health per person every 15 years. Furthermore, there are large inequalities evident, with 18 years difference in HALE evident in England between the lowest and highest Index of Multiple Deprivation (IMD) groups (ONS, 2018). This trajectory is unsustainable for NHS and social care delivery. The UK Government's 'Ageing Society' Grand Challenge set a mission to increase HALE by 5 years (from 63 to 68 years) by 2035, with the planned *NuLifE* programme in direct response to this ambitious target (BEIS, 2019).

Suboptimal diet is the number one modifiable determinant of HALE and chronic disease risk globally, and, in the UK, is responsible for 15–20% of the population attributable fraction of years of life lost (Afshin et al., 2019; Steel et al., 2018). Current UK dietary recommendations and public health policy are based largely on evidence from prospective cohort studies. There is limited evidence from efficacy trials which typically examine the short-term impact of select dietary components or foods on biochemical, functional and imaging-based surrogate markers of disease, as the primary endpoint. The actual impact and size effect of a whole diet intervention on incident disease is completely unknown. In addition, the approaches necessary to implement such an intervention by achieving long-term changes in individual and community eating behaviour are unidentified and untested.

The remit for a *NuLifE* primary prevention trial is therefore important and timely. The long-term aim of the programme is to establish the impact of a whole-diet nutrition intervention on the risk of transition from health to a clinical diagnosis of disease in 'at-risk' UK adults.

AIMS OF THE WORKSHOP

1. Fully consider the need for and impact of the *NuLifE* trial.
2. Develop linkages between disciplines (nutrition, trialists, primary and secondary care, health economics, digital health, behavioural science, food industry/retailer, the public) and identify discipline gaps.
3. Advance the research questions and trial design.
4. Develop a plan and timeline for delivering the *NuLifE* programme and funding strategy.

WORKSHOPS STRUCTURE

The workshop was delivered as two half-day virtual events, held on the 28th September 2020 and the 17th February 2021. Prior to the first meeting, the following documents were provided to all registered participants to show the relevant policy and scientific background to the *NuLifE* remit.

- A summary of the workshop bid to the MRC
- Infographic of the UK Eatwell Guide (PHE, 2016a)
- Public Health England's dietary recommendations for the UK 2016 (PHE, 2016b)
- Mortality and life expectancy trends in the UK (Marshall et al., 2019)
- *Advancing our Health: Prevention in the 2020s* (Department of Health & Social Care, 2019)
- World Health Organization: *Risk reduction of cognitive decline and dementia 2019* (WHO, 2019)
- Schulze M et al., Food based dietary patterns and chronic disease prevention (Schulze et al., 2018)
- Scheelbeek P, Dangour A et al., Health impacts and environmental footprints of diets that meet the Eatwell Guide recommendations: analyses of multiple UK studies (Scheelbeek et al., 2020)
- Slide sets summarising previous nutrition randomised controlled trials (*Nu-AGE*, *CRESSIDA*, *PREDIMED*, *Food4Me*, *MedEx*) (Berendsen et al., 2018; Celis-Morales et al., 2017; Estruch et al., 2018; Reidlinger et al., 2015; Shannon et al., 2021)

NULIFE WORKSHOP 1

Key presentations

The first *NuLifE* workshop began with an overview of the workshop justification from AMM. To inform the possible disease end-point focus for *NuLifE*, AMM presented the UK LE, HALE and morbidity and mortality statistics. Dementia is the number one cause of mortality in England and Wales accounting for 12.8% of total deaths in 2017, with dementia and cardiovascular

diseases collectively responsible for 40% of total deaths (ONS, 2017). Two-thirds of the UK population are either overweight or obese, with a greater prevalence in those who are most deprived (NHS Digital, 2020). Reflecting on key UK nutrition and dietary guidelines as operationalised in the Eatwell Guide, and current population diet and nutrition data, large proportions of the population are not meeting current dietary targets and there is an evident socio-economic gradient (Bates et al., 2019). In a 2020 analysis using data from 2012 to 2017 in the *National Dietary and Nutrition Survey (NDNS)*, population adherence for nine of the Eatwell Guide recommendations ranged from 7% to 80%, with the lowest adherence for fibre, oily fish and sugar (Scheelbeek et al., 2020).

To fuel breakout room discussions, and put the subsequent key presentations into perspective, AMM presented some initial thoughts (and related questions) around the potential PICO (i.e. population, intervention, control, outcome) elements of the *NuLifE* trial (Richardson et al., 1995). For the 'Population' element, the trial would likely need to recruit participants with an 'at-risk' profile in order to achieve the required number of disease cases during the intervention period (but how do we define 'at-risk'?). For the 'Intervention', should we adopt a whole-diet approach, rather than focus on specific nutrients, dietary derived bioactives or select foods/food groups? Should the intervention be bespoke and personalised? Should the trial be a pragmatic, effectiveness trial? For the 'Control' arm, should it be usual care? For the 'Outcome' element, do we focus on incident cardio-metabolic disease, should we include dementia, and should our composite end-point include other major chronic diseases such as diet-sensitive cancers?

Lastly, AMM set out a crude sample size calculation to set the expectations of attendees to the likely scope of the trial. Using event rates from the large prospective UK *Biobank* study of 0.5 million adults in the UK, with a high-risk population over the age of 55 years, a composite outcome of cardiovascular disease and type 2 diabetes with an event rate of approximately 3% a year would give a simple two-arm trial over 5 years a power of 90% to detect a 10% relative risk reduction if there were approximately 16 000 participants (UK Biobank, 2007).

The following speakers and breakout room discussions expanded on these key elements of trial design and the necessary research infrastructure that would be needed for a nutrition trial that was much larger than any that had been previously attempted in the UK (with only a few examples globally; Estruch et al., 2018).

Jane Armitage from the University of Oxford spoke about how new opportunities with digital technologies and data linkage could enhance the ability to run streamlined trials at scale with lower costs and improved quality. Giving examples from the large-scale *ORION-4* and *ASCEND* trials (ClinicalTrials.gov Identifier: NCT03705234; NCT00135226), she highlighted the importance of simple inclusion criteria; and the use of electronic health records to identify large numbers of participants, screen and consent them efficiently, and follow them up more completely for a wide range of events (Mafham et al., 2020).

Falko Sniehotta from the University of Newcastle gave a summary of the particular challenges of

TABLE 1 Summary of Population, Intervention, Control, Outcome (PICO) elements discussed during breakout rooms in *NuLifE* workshop 1

PICO breakout room	Main discussion points
Population	• Challenges of working in deprived areas, but possible target for greatest effect • Using GP surgeries to recruit high-risk patients • Potential screening for those with low-quality diets at baseline (vs. using streamlined recruitment methods)
Intervention/Control	• A whole-diet approach (e.g. Eatwell Guide) • Consideration of sustainability • Personalised tailoring of intervention elements with web-based tools • Involvement of retailers • Consideration of difficulties that takeaway food differs across the country, and general difficulties of randomisation in a whole-diet approach • Control group is usual care for high-risk groups
Outcome	• Composite outcome to increase number of events • Need a clear causal pathway targeted by nutrition over a 5-year period • Previous nutrition efficacy trials have shown effects on intermediate mechanisms for cardiometabolic diseases like cardiovascular disease and diabetes • Need a different outcome for an interim pilot study, such as blood pressure, that would demonstrate efficacy of the intervention quickly • What to do about weight loss? Is this an outcome to aim for, or would it confuse the picture?
Study design	• Effectiveness or efficacy trial? • Factorial design with personalised tailoring

TABLE 2 Evidence synthesis of randomised controlled trials using behaviour change to improve diet in the last 5 years

Author	Year	Intervention groups	Participants	Duration
Cho et al. (Cho et al., 2020)	2020	1. nonuser group (control), 2. app-based diet and exercise self-logging group (app only) 3. app-based self-logging and personalised coaching	30–59 years two metabolic abnormalities *n* = 129	6 months
Yubero-Serrano et al. (Delgado-Lista et al., 2016; Yubero-Serrano et al., 2020) [*CORDIOPREV*]	2020	1. Mediterranean Diet 2. Low-fat diet	>20 & <76 years, established heart disease without clinical events in the last 6 months *n* = 1002	7 years
Rijnaats et al. (Rijnaarts et al., 2020)	2020	1. Personalised dietary advice (PDA) 2. General advice (GA)	>18 years Apparently healthy Low fibre intake *n* = 246	6 weeks
Hackshaw-McGeagh et al. (Hackshaw-McGeagh et al., 2019) [*PrEVENT*]	2019	1. Plant based diet [Fruit/veg (FV) and low dairy] 2. Lycopene 3. Control	Males with prostrate cancer *n* = 81	6 months
Kushida et al. (Kushida et al., 2019)	2019	1. 1975 Japanese diet (JD) 2. Modern Diet (MD)	20–30 years Healthy *n* = 32	4 weeks
Piernas-Sanchez et al. (Piernas et al., 2020; Piernas et al., 2019) [*PC-SHOP*]	2019	1. Control 2. Health professional advice (HPA) 3. HPA and grocery shopping feedback	>18 years Raised LDL-C *n* = 113	3 months
Duś-Żuchowska et al. (Duś-Żuchowska et al., 2018)	2018	1. Mediterranean Diet 2. Central European Diet	Post-menopausal *n* = 144	16 weeks
Katsagoni et al. (Katsagoni et al., 2018)	2018	1. Control 2. Mediterranean diet (MD) 3. Mediterranean lifestyle (ML)	18–65 With non-alcoholic fatty liver disease *n* = 63	6 months
Kazemi et al. (Kazemi et al., 2018)	2018	1. Pulse-based diet 2. Healthy control diet	Polycystic ovary syndrome *n* = 61	16 weeks
Krishnan et al. (Krishnan et al., 2018)	2018	1. Typical American Diet (TAD) 2. Dietary Guidelines America diet (DGA)	Overweight to obese women, less than 150 min/week physical activity ≥1 cardiometabolic risk factor *n* = 52	8 weeks
Properzi et al. (Properzi et al., 2018)	2018	1. Mediterranean Diet (MD) 2. Low-fat diet	Non-alcoholic fatty liver disease *n* = 51	12 weeks
Winkvist et al. (Winkvist et al., 2018; Vadell et al., 2020)	2018	1. Anti-inflammatory diet 2. Typical diet	Rheumatoid arthritis ≥2 years, 18–75 years *n* = 50	10-week (cross-over)
Jayawardena et al. (Jayawardena et al., 2017)	2017	1. Control 2. 'Plate model' Intervention	Post-myocardial infarction *n* = 120	12 weeks
Koutoukidis et al. (Koutoukidis et al., 2017; Koutoukidis et al., 2019) [DEUS]	2017	1. Control 2. Shape-up intervention	Women >18 years Endometrial cancer *n* = 54	8 weeks

Outcomes	Behaviour change components	Dietary change	Results
Blood pressure, weight, waist circumference, body fat, HOMA-IR and lipids	Personalised feedback (Group 3) Self-monitoring (Group 2 + 3)	Not reported	Personalised feedback not more effective than self-monitoring
Cardiovascular events	Personalised interviews, group education sessions and food provision to both groups	Differences in adherence to the 14 items of the MEDAS after 1 year	Study ongoing
Fibre intake	Personalised advice (web-based service)	Participants in the PDA group were more likely to adhere to fibre recommendations	–
Adherence (based as 90% of time)	Printed instructions (group 1) Supplements (group 2)	40% adhered to FV 72% adhered to dairy 79% adhered lycopene	–
Change in gut microbiota	Three meals daily pre-prepared food (both groups)	Not reported	Taxa significantly changed after consumption of JD
Saturated fat intake (SFA)	Personalised feedback (Group 3) Advice session (COM-B behaviour change wheel) (Group 2 and 3)	No difference in SFA intake or food purchasing between groups	No difference in lipid profiles compared to control
Asymmetrical dimethylarginine (ADMA) and C-reactive protein (hs-CRP)	Pre-portioned main meals (covering 35% of energy) delivered (both groups)	Not reported	No between-group differences in ADMA or hs-CRP
Liver enzymes (ALP and ALT) Liver stiffness Weight loss Adherence	MD and ML 7 x 1 h group sessions based on goal setting theory ML – diet + activity and sleep	ML and MD improved MD adherence (FFQ and 24-h recall)	MI – improved ALT and liver stiffness ML and MD – weight loss
Cardiometabolic measures	Two meals (i.e., lunch and dinner) were supplied daily for participants in the pulse-based diet group	Differences in fibre and micronutrient intakes between groups (24-h recalls)	Pulse-based diet decreased total insulin AUC, levels of LDL-C, TG, TC/HDL-C ratio, diastolic blood pressure, and increased HDL-C compared to control diet
Glucose homeostasis and fasting lipids	All meals provided	30 ± 35 (10.4% ± 0.1% deviation) instances of reported deviance from full dietary compliance in the DGA group and 39 ± 31 (13.9% ± 0.1%) instances of reported deviance in the TAD group	No between-group differences in primary outcomes
% of hepatic steatosis (HS)	Food provision (both groups) Nuts and olive oil for the MD Natural muesli and low-fat snack bars for the low-fat diet Personalised dietary advice (both groups)	Dietary change achieved in both groups (Diet History)	HS reduced in both groups
Disease severity	Food provision (both groups) equivalent 50% of the daily intake during 5 weekdays	Intakes of fibre, EPA, and DHA were considerably higher during the intervention period (3-d diet record)	No significant differences between groups
Weight Blood pressure (BP) Lipids	Personalised advice	Not reported	Weight reduction relative to control. No change in BP or lipids
Adherence to AHEI 2010 score Quality of Life (QoL)	Group sessions	77% adhered to intervention (AHEI results not reported)	Adherence improved but not QoL

(Continues)

TABLE 2 (Continued)

Author	Year	Intervention groups	Participants	Duration
Ananad et al. (Anand et al., 2016)	2016	1. Control 2. Digital health intervention	>30 years South Asian *n* = 343	1 year
Wong et al. (Wong et al., 2016)	2016	1. Control 2. Intervention	40–70 years Hypertension *n* = 556	1 year

Abbreviations: AHEI, alternative healthy eating index; ALP, Alkaline phosphatase; ALT, alanine aminotransferase; AUC, area under the curve; DHA, docosahexaenoic acid; EPA, eicosapentaenoic acid; FFQ, food frequency questionnaire; HDL-C, high-density lipoprotein cholesterol; HOMA-IR, Homeostatic Model Assessment for Insulin Resistance; LDL-C, low-density lipoprotein-cholesterol; MEDAS, Mediterranean Diet Adherence Screener; TC, total cholesterol; TG, triglyceride.

behavioural interventions at scale, with a focus on fidelity, adherence, effectiveness and efficacy. He summarised that a whole systems approach was needed for complex behavioural interventions, which complicated the evaluation and interpretation of the trial result, but would be more likely to facilitate maintenance of changed behaviour over time and improve health outcomes.

Finally, Paul Aveyard from the University of Oxford spoke about the trial design options. This started with a reminder of the MRC Framework for complex intervention development and reinforcing the value of defining the behavioural theory underpinning the putative intervention (Craig et al., 2008). Given this is a trial aiming for a long-term health outcome, it is vital to ensure the intervention had the best chance of achieving sustained dietary change. The presentation then passed on to novel trial designs that may be employed in early-stage development work, such as the multiphase optimisation strategy trial design, that can help determine the effect of particular components of an intervention, and the value of adaptive designs in finding ways to maximise the benefit of a behavioural support programme (Wyrick et al., 2014). Finally, he presented an explanatory-pragmatic trial continuum to fuel debate about which end of the spectrum we would want to situate this work.

Breakout rooms and general discussion

Four breakout rooms then discussed the PICO elements on the study design in depth, and fed back to the entire group their main points. See Table 1 for a summary of the discussed PICO elements.

When the breakout rooms fed back to the final discussion, a consensus emerged that there was a need and a will to proceed with the *NuLifE* programme. It was noted that it was especially important to consider how such a trial might help address health inequalities, perhaps by recruiting specifically in areas of high deprivation. The other main area of discussion was whether *NuLifE* would be an efficacy trial, focussed on answering the question of the strength of the impact of a healthy diet on the risk of disease outcomes; or an effectiveness trial, demonstrating the impact of a pragmatic dietary intervention on a representative sample of the UK.

Subsequently between workshops, comments were sought online on three possible study designs.

1. An individual-level efficacy (explanatory) RCT aiming to change dietary behaviours and reduce incident disease in UK adults.
2. An individual-level effectiveness (pragmatic) RCT aiming to change dietary behaviours and reduce incident disease in UK adults.
3. A population-level cluster (area/town/city) RCT aiming to influence structural (social, cultural, economic, geographical and other environmental) determinants of eating behaviour, improving eating behaviour and nutrient status in UK adults, and reducing the risk of incident disease in UK adults.

NULIFE WORKSHOP 2

At the start of the second *NuLifE* workshop, AMM began with a summary of the first workshop and the online working documents. The online working document of potential study designs between sessions had reached an agreement that there was insufficient justification to proceed with an explanatory RCT (#1 above) for the following reasons:

- To run a true whole-diet efficacy RCT with long-term outcomes, we would need to be very confident of the ability to implement an intervention with high fidelity, and with a compliant (pre-screened, selected and monitored) population group, to have the power to detect outcomes. It would be practically very challenging to get the compliance needed for the level of certainty required.
- Furthermore, such an approach would likely divert attention from populations where there is greatest need (i.e. participants in communities with high levels of deprivation).

Outcomes	Behaviour change components	Dietary change	Results
Myocardial infarction risk score	Stages of change motivational message and health tips every 2 weeks	Not reported	No change between groups
10-year cardiovascular risk	Counselling session (1 × 25 min) and individualised meal plans	Not reported	No change between group

- An efficacy trial would need to be followed by effectiveness trials if the results are going to inform public health policy.
- As a result, the higher priority and best use of resources would be to conduct a pragmatic trial in deprived communities where the poorest adherence to dietary guidelines is evident. Such a trial is likely to be more informative and impactful than a similarly sized trial in the general population.

Although there was a strong rationale for a cluster intervention approach (#3 above), which focussed on contextual modulators of eating behaviour, the development of such an intervention appeared currently unrealistic as it would be reliant on enactment of several fiscal, food and health-related policy changes; and a much greater understanding of the relative structural determinants of food purchasing and eating behaviour than is currently available.

The consensus was clear, that *NuLifE* would proceed with planning an effectiveness (pragmatic) trial focussed on examining the impact of an eating behaviour intervention on incident disease in communities with a high score on the IMD.

Such an approach is aligned with the public health policy need as reflected in:

1. the UK Government *Ageing Society Grand Challenge* mission (BEIS, 2019);
2. the Public Health England's Strategy 2020–2025, around healthy inequalities and healthy ageing (PHE, 2019);
3. current health and behaviour inequalities, aggravated and highlighted by the COVID-19 pandemic and its impact on COVID-19 prognosis (Bambra et al., 2020);
4. reports such as *Health equity in England*: *The Marmot review 10 years on* (Marmot, 2020).

Prior to the second meeting, the working group agreed that it was clear we were lacking a consensus on the intervention approach for *NuLifE*. It was decided that we needed an evidence synthesis of eating behaviour interventions to help inform the discussion.

Evidence synthesis of eating behaviour interventions

Changing eating behaviour is hugely challenging, with numerous social, cultural, economic, environment and geographical variables influencing food purchase and consumption. Prior to workshop 2, a systematic search of the empirical evidence was conducted by AJ (University of East Anglia) to inform the discussion and to establish the evidence for the impact of various interventions on attainment and maintenance of eating behaviour change. Search terms looked for any RCT on diet and disease in adults that did not involve supplements, which was published since 2015; the search was extended to also look for any RCTs on diet conducted in the UK since 2010. Results were excluded if the trials did not involve behavioural change or were lacking diet-only treatment arms (see Appendix B for more details). The following intervention approaches were focussed on and summarised, along with their results:

1. food/meal provision
2. cash incentives, food vouchers, supermarket delivery
3. digital intervention
4. personalisation
5. education and cookery skills
6. Behaviour Change Technique (BCT)-based
7. group sessions and peer support
8. community-based intervention.

Results from trials run in the last 5 years are summarised in Table 2 (further results are in Appendix B). Many trials were conducted in healthy individuals who were not selected on the basis of the quality of their diet and hence many had adequate diets at baseline. A range of dietary components were targeted and, in many cases, an exact definition of dietary improvement was not detailed. It was therefore difficult to conclude if the studies that reported no effect on health outcomes were due to poor adherence or a true lack of effect. With such heterogeneity in the results, it was not possible to reach a consensus on which whole diet intervention

approaches would be most likely to provide individuals, families and communities with the capability, opportunity and motivation to enact and maintain eating behaviour change. It was also clear that research aimed at enacting dietary behaviour change in deprived communities was particularly scarce.

Presentations and breakout rooms focussed on intervention

The presentations and breakout room discussions for the second workshop all focussed around defining an effective eating behaviour intervention. First, spokespeople from previous whole-diet interventions (JM from *Food4Me*, AJ from *NuAge*, Wendy Hall from *CRESSIDA*, AMM from *MedEx*) summarised key insights from their studies (details of these studies are summarised in Appendix B).

Breakout rooms chaired by members of the working group (NS, SJ, JC, JM) then discussed the intervention components as a first priority, and the study population or key endpoints as a second priority. Feedback and general discussion amongst the entire group revealed that there was a general enthusiasm for targeting groups with high IMD scores of deprivation as a unique component of *NuLife*. However, there was also a consensus that the *NuLifE* trial would need to be conducted in stages in order to achieve its ultimate goal, requiring a strong community co-creation, pilot and feasibility phase in order to proceed with confidence with an eating behaviour intervention strategy which is fit for purpose.

STAGE 1: TAILORING COMPLEX DIETARY INTERVENTIONS TO COMMUNITIES WITH A HIGH INDEX OF MULTIPLE DEPRIVATION

Stage 1 of the *NuLifE* programme will be a community-based (high IMD communities), Patient and Public Involvement informed, project to co-design, develop and test the *NuLifE* intervention approaches to increase the agency of residents to enact eating behaviour within the Eatwell guidelines. The intervention will be developed based on the MRC *Developing and evaluating complex intervention* guidelines (Craig et al., 2008). In addition, the intervention will be co-developed and co-produced with organisations such as the Integrated Care Systems, Community Foundations, FoodBanks/Trussell Trust, community-embedded food retailers (e.g. Co-op/ALDI) and build on existing community assets. Both personalised (to the individual's baseline health and eating behaviour status) and contextual intervention components will be considered, with the ultimate aim to provide individual and communities with the capability, opportunity and motivation to enact healthier eating behaviours which aim to increase HALE and reduce chronic disease onset (Michie et al., 2011).

STAGE 2: ONE-YEAR EFFECTIVENESS TRIAL ON INTERIM END POINT OF BLOOD PRESSURE

The *NuLifE* consortium then agreed that Stage 2 of the *NuLifE* programme would be an interim step to test the effectiveness of a one-year intervention of the *NuLifE* approach with blood pressure as the primary endpoint. Blood pressure is a robust target due to its strong prognostic value for future cardiovascular diseases, and it is influenced by a wide array of foods and macro- and micro-nutrients and non-nutrient bioactives (Jennings et al., 2019; Ndanuko et al., 2016).

STAGE 3: LARGE-SCALE EFFECTIVENESS PRIMARY PREVENTION RCT

Finally, Stage 3 would be to run a full effectiveness primary prevention RCT of the *NuLifE* intervention to assess the effect on incident disease.

CONCLUSION

We thank the MRC for funding this workshop, which provided the impetus for over 40 experts from a range of disciplines to come together over 6 months. Through two workshops, along with online discussions and a systematic evidence synthesis, the first UK nutrition, primary prevention, effectiveness trial took shape. The workshops delivered a three-stage plan with the ultimate ambitious aim of establishing a multi-disciplinary and multi-agency approach, alongside effective eating behaviour change strategies, to address the growing inequalities in the UK and contribute to a reduced risk of prevalent diet-related chronic disease and increased HALE. Such an approach directly addresses the Government's 'Ageing Society' Grand Challenge to 'ensure that people can enjoy at least 5 extra healthy, independent years of life by 2035, while narrowing the gap between the experience of the richest and poorest' (BEIS, 2019).

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JC and AMM drafted the manuscript; JM, SFT, SJ, NS, AJ all assisted with creating, editing and revising the manuscript.

CONFLICT OF INTEREST

No conflicts of interest.

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APPENDIX A

WORKSHOP ATTENDEES

Surnames	First Name	Organisation	Expertise/Research Interests
Ángel Martínez González	Miguel	Universidad de Navarra	Mediterranean diet and health, PREDIMED
Armitage	Jane	University of Oxford	large-scale clinical trials in cardiovascualr disease
Aveyard	Paul	University of Oxford	behavioural medicine, weight loss, disease prevention or treatment
Brayne	Carol	University of Cambridge	neuroscience, epidemiology, aging
Cade	Janet	University of Leeds	nutritional epidemiology, diet assessment methods
Calder	Philip	University of Southampton	nutritional modulation of immunity, inflammation and disease risk
Carter	Jennifer	University of Oxford	nutrition, adiposity, epidemiology and statistics
Clarke	Philip	University of Oxford	health economics, health inequalities, diabetes
Curtis	Peter	UEA	diet, fruit and vegetables, flavonoids, RCT, cardiovascular
Daley	Amanda	Loughborough University	lifestyle interventions within health care and health
Dobson	Paul	UEA	business strategy, public policy, food supply and retailing
Dye	Lousie	University of Leeds	nutrition and cognitive function across the lifespan
Fairweather-Tait	Susan	UEA	micronutrients and health
Gill	Jason	Glasgow University	metabolic responses to exercise and diet
Godfrey	Keith	University of Southampton	nutritional epidemiology and human development
Gray	Cindy	Glasgow University	health behaviour change
Gray	Alastair	University of Oxford	health economics, large randomised trials
Griffin	Bruce	University of Surrey	nutritional biochemistry, lipid metabolism, health
Haczewski	Tom	The User Story SME, Norwich	evidence-based digital product business
Hall	Wendy	KCL	nutritionist, clinical trials, public health policy
Haynes	Richard	University of Oxford	large clinical trials in cardiovascular and metabolic disease
Hornberger	Michael	UEA	applied dementia research
Hunt	Kate	University of Stirling	behaviour change and health inequalities
Jackson	Kim	University of Reading	dietary fats, genotype, lipoprotein metabolism
Jebb	Susan	University of Oxford	trials, weight loss, diet and obesity-related diseases
Jennings	Amy	UEA	diet, ageing, microbial and metabolite profiles, health
Lietz	Georg	University of Oxford	micronutrients, nutrigenomics, inter-individual variation
Lovegrove	Julie	University of Reading	nutigenetics, nutrigenomics, cardiovascular disease
Mathers	John	Newcastle University	aging, nutrition, molecular biology, epidemiology
McNulty	Helena	University of Ulster	nutrition-related health issues, food and health policy
Mela	David	Consultant (Food Industry)	nutritional science and metabolic health
Milne	Eugene	Newcastle Public Health	Director of Public Health, inequalties
Minihane	Anne Marie	UEA	diet, nutrigenetics and cardio-metabolic and cognitive health
Naughton	Felix	UEA	phone interventions to support health behaviour change
Petrou	Stavros	University of Oxford	health economics, trial-based economic evaluations

Surnames	First Name	Organisation	Expertise/Research Interests
Rogers	Peter	University of Bristol	nutrition, behaviour, obesity and psychological health
Sattar	Naveed	Glasgow University	epidemiology of diabetes, obesity and heart disease
Smith	Louise	Norfolk Public Health	Director of Public Health, health and wellbeing
Sniehotta	Falko	Newcastle University	trials, behavioural change, health
Whitty	Jenny	UEA	applied health economist
Wildman	John	Newcastle University	health economics, health inequalities

APPENDIX B

SYSTEMATIC SEARCH OF THE EMPIRICAL EVIDENCE ON EATING BEHAVIOUR CHANGE INTERVENTIONS

What is the evidence for the impact of various interventions on attainment and maintenance of eating behaviour change?

Randomised controlled trials using behaviour change to improve diet (focused on whole diet).

PUBMED SEARCH [1]

randomized controlled trial AND diet AND disease AND ((double blind OR single blind)) AND adult NOT supplement

Filter 2015–2021

[*n* = 391]

Excluded studies reporting single dietary components or supplements, multi domain interventions, without clearly defined behaviour change elements or lacking diet only treatment arms.

Results reported in main text.

PUBMED SEARCH [2]

Randomized controlled trial AND diet AND disease AND ((double blind OR single blind)) AND adult NOT supplement AND ((United Kingdom) OR UK).

Filter 2010–2021

[*n* = 94]

Excluded studies reporting single dietary components or supplements, multi domain interventions, without clearly defined behaviour change elements, lacking diet only treatment arms or not conducted in the UK.

Results reported in Table B1.

ADDITIONAL STUDIES [3]

Large nutritional studies not covered above.

1. PREDIMED
2. Food4Me
3. NuAGE
4. CRESSIDA
5. MedEx

TABLE B1 Randomised controlled trials using behaviour change to improve diet in the UK in the last 10 years

Hackshaw_ McGeagh al.[5] [PrEVENT]	2019	1. Plant based diet (fruit and veg [FV] and low dairy) 2. Lycopene 3. Control	Males with prostate cancer *n* = 81	6 months	Adherence (based as 90% of time)	Plant based diet and lycopene	Printed instructions (group 1) Supplements (group 2)	–	40% adhered to FV 72% adhered to dairy 79% adhered lycopene
Piernas-Sanchez et 7, 8 [PC-SHOP]	2019	1. Control 2. Health professional advice (HPA) 3. HPA and grocery shopping feedback	>18 years Raised LDL-C *n* = 113	3 months	Saturated fat (SFA) intake	SFA	Personalised feedback (Group 3) Advice session (COM-B behaviour change wheel) (Group 2 and 3)	No difference in lipid profiles compared to control	No difference in SFA intake or food purchasing between groups
Koutoukidis et al. 17 [DEUS]	2017	1. Control 2. Shape-up intervention	Women >18 years Endometrial cancer *n* = 54	8 weeks	Adherence QoL	Adherence to Alternative Healthy Eating Index 2010 score	Group sessions	Adherence improved but not QoL	77% adhered to intervention (AHEI results not reported)
Anderson et al.[21]	2014	1. Diet and physical activity intervention 2. Control	50–74 years polypectomy for adenoma, BMI >25 *n* = 329	12 months	Weight	British Heart Foundation recommendation	Motivational interviewing Energy intake goal Self-monitoring Personalised diet	Significant difference in weight loss between groups	Decrease in high fat food Increase in FV
	2014	1. Healthy living intervention 2. Control	16–35 years Psychosis diagnosis *n* = 105	12 months	BMI	Good/bad food score	Face-to-face sessions Patient led goals and action plans Cooking groups (optional)	No significant differences in BMI	Food score improved relative to control
Gibson et al.[23]	2012	1. FV diet – 5 portions/day 2. Low FV diet – 2 portions/day	65–85 years <2 portions FV *n* = 83	16 weeks	Antibody response to vaccination	FV	Extensive personal dietetic advice and nutritional counselling. FV deliveries (both groups)	A greater specific antibody response to Pneumovax II vaccination	Change in FV consumption differed significantly between groups

Abbreviations: LDL-C, low-density lipoprotein cholesterol; QoL, Quality of Life.

Results reported in Table B2.

TABLE B2 Large nutritional studies not covered above

Study	Intervention groups	Participants	Duration	Dietary component	Behaviour change components	Dietary change
PREDIMED24	1. Mediterranean diet +olive oil 2. Mediterranean diet +nuts 3. Control (low-fat diet)	55–80 years high cardiovascular risk *n* = 7447	4.8 years	MD	Individual and group sessions Food provision (all groups)	2 MD groups significantly increased fish and legumes compared to control +nuts or olive oil depending on group assignment
Food4me25	1. Conventional dietary advice (control) PN advice based on: 2. Individual baseline diet; 3. Individual baseline diet plus phenotype (anthropometry and blood biomarkers); 4. Individual baseline diet plus phenotype plus genotype (five diet-responsive genetic variants)	18–79 years *n* = 1607	6 months	National dietary recommendations	Personalized feedback reports	Individuals receiving PN advice consumed less red meat (8.5%) and less salt (6.3%), had lower energy intake (4.4%) and higher HEI scores (2.6%) when compared with the Control group
NUAGE26	1. Mediterranean diet 2. Control (usual diet)	65–79 years Apparently healthy *n* = 1296	12 months	MD	Food provision Monthly dietary counselling based on motivational interviewing and stage of change Individually tailored dietary advice	Significant increase in MD adherence was found in the diet group compared to the control group
CRESSIDA27	1. UK dietary guidelines 2. Traditional UK dietary pattern	40–70 years Healthy *n* = 165	12 week	UK dietary guidelines	Face-to-face meetings Food provision	Protein and dietary fibre intakes were 2.1% energy and 7.6 g/d higher; Fat, and SFA and *trans* fatty acid intakes were 3.4%, 7.2%, and 0.6% energy lower, and those of MUFAs and PUFAs were 3.4% and 1.9% higher; the intake of long-chain n–3 PUFAs was 1.3 g/d higher; sodium intake was 65 mmol/d lower; and potassium intake was 12 mmol/day greater
MED-EX	1. Mediterranean diet (MD) 2. MD + physical activity (PA) 3. Control (usual diet)	55–74 years QRISK2 score of ≥10% Low PA and MD adherence *n* = 108	24 weeks	MD	Web-based intervention Group sessions Food delivery	Ongoing

Abbreviations: HEI, Healthy Eating Index; MUFA, monounsaturated fat; PUFA, polyunsaturated fat; SFA, saturated fat.