Supplement 1

Checklist: factors to be considered, and recommendations for best practice when designing, conducting and reporting human intervention studies to evaluate the health benefits of foods

Phase	Factors to consider	Recommendations for design and conduct	Recommendations for reporting	Reported on line No
Design	Hypothesis	Clear hypothesis	Explicitly state hypothesis, link to primary outcome measures	81-85
	Study design	Appropriate design	Clearly describe, with rationale	114-132
	Duration	Appropriate to design, intervention and outcome measures	Clearly describe, with rationale	114-132
	Intervention	Test and control products suitably matched	Describe test and control products in detail, with rationale	114-132
	Amount	Appropriate to outcome measures and to practical usage	Clearly describe, with rationale	114-132
	Outcome assessment	Define primary outcomes and methods of measurement	Clearly describe how and when assessed and link to hypothesis	89-113, 134-151
		Define all secondary outcomes and methods of measurement	Clearly describe how and when assessed	89-113
	Eligibility criteria	Define all eligibility criteria	Describe criteria using objective, quantitative descriptors where possible	89-113
	Statistical considerations			
	Randomisation	Use randomised design where possible and ensure appropriate method for allocation sequence generation and concealment	Clearly describe randomised design and the methods used for randomisation, sequence generation and concealment	114-132
	Blinding	Ensure double blinding if feasible, single blinding if not	Describe how blinding was achieved (who was blinded and how), report success rate	114-132
	Size of study	Conduct power calculation based on primary outcome measures	Include all elements of power calculation	114-132
Conduct	Study protocol			
	Ethical approval and trial registration	Obtain full ethical approval, register trial, comply with the Declaration of Helsinki	Give details of research ethics authority and approval number, and database and registration number	81-85
	Recruitment	Define recruitment strategy and process, including settings and dates	Explicitly describe strategy, provide participant flow diagram	81-85
	Data collection			
	Background diet and monitoring change	Select suitable methods to collect and analyse data	Describe assessment and analysis methods, report descriptive data on background diet and changes for all components that may be relevant by allocated intervention group	114-132 114-132
	Background health status and lifestyle, and monitoring changes	Define relevant measures, select suitable methods of assessment	Justify relevant measures, describe assessment methods, and report relevant factors and changes by allocated intervention group	81-85
	Unintended effects	Devise strategy and methods to capture data	Report methods to assess unintended effects and report by allocated intervention group	114-132
	Adverse events	Have mechanisms in place to record and respond to adverse events	Clearly define and report all adverse events by allocated intervention group	106-109
	Compliance	Define acceptable levels of compliance, use appropriate strategies to maximise compliance, select and use rigorous but feasible methods for assessment of compliance	Report methods used to measure and maximise compliance, report compliance rates numerically and by allocated intervention groups	128-132
Analysis and interpretation	Statistical analysis	Devise appropriate analysis methods, based on study design and outcome measures	Describe distribution of data, present descriptive characteristics by allocated intervention group, present hypothesis tests for comparing allocated intervention groups, make clear distinction between primary v. secondary endpoint analyses, state whether analysis ITT or PP	175-181
	Discussion and interpretation	Consider study limitations and generalisability of findings	Discussion of limitations and generalisability of study findings	386-396
	Conclusion	Relate directly to hypothesis, study design, test product and study participants	Clear statement of conclusion	398-405

ITT, intention to treat; PP, per protocol.

Welch RW, Antoine JM, Berta JL, Bub A, de Vries J, Guarner F, Hasselwander O, Hendriks H, Jäkel M, Koletzko BV, Patterson CC, Richelle M, Skarp M, Theis S, Vidry S, Woodside JV; International Life Sciences Institute Europe Functional Foods Task Force. Guidelines for the design, conduct and reporting of human intervention studies to evaluate the health