Table 1: The standard CONSORT 2010 items to the left, with proposed CONSORT-Equity extensions to the right

Section	Item	Standard CONSORT Item	Proposed Extension for Equity	Pg.
Title				
Title	1a	Identification as a randomised trial in the title	If health equity is a major focus, consider using the term "health equity" in the title.	
Abstract				
Structured Summary	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	State research question(s) related to health equity	
	1c		Present results of all planned health equity analyses	
	1d		Describe extent and limits of applicability to populations of interest across PROGRESS-Plus characteristics	
Introduction				
Background	2a	Scientific background and explanation of rationale	Describe rationale for focus on health equity	
Objective	2b	Specific objectives or hypotheses	State the-objective being addressed with reference to health equity	
Methods				
Trial Design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Describe aspects of trial design that were chosen to answer equity questions	

	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons		
Participants	4a	Eligibility criteria for participants	Report population eligibility criteria across relevant PROGRESS-Plus characteristics.	
	4b	Settings and locations where the data were collected	Report context and relationship to health inequity	
	4c		Report details of partnerships with populations and communities, where applicable.	
Intervention	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Report whether comparator intervention is the standard of care, and whether it has equity implications.	
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Report whether outcomes were identified as relevant and important to population(s) across PROGRESS-Plus characteristics and how this was done	
	6b	Any changes to trial outcomes after the trial commenced, with reasons		
Sample Size	7a	How sample size was determined	Report whether analyses focused on health equity objectives are powered to detect differences.	
	7b	When applicable, explanation of any interim analyses and stopping guidelines		
Randomisation Sequence Generation	8a	Method used to generate the random allocation sequence		
	8b	Type of randomisation; details of any restriction (such as	Report whether randomisation was stratified on PROGRESS-	

		blocking and block size)	Plus characteristic(s)	
Allocation Concealment Mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned		
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions		
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how		
	11b	If relevant, description of the similarity of interventions		
Statistical Methods	12a	Statistical methods used to compare groups for primary and secondary outcomes		
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Report details of additional analyses focused on health equity, including whether analyses to estimate heterogeneity of effects between population subgroups were done on an additive or multiplicative scale, and whether pre-specified.	
Ethical Concerns	a	New item**	Report details of ethical clearance and informed consent	
Results				
Participant flow (a diagram is strongly	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analyzed for the primary outcome	Describe for each group, numbers of participants who were assigned, received and who were analyzed across relevant PROGRESS-Plus characteristics	

recommended)				
	13b	For each group, losses and exclusions after randomisation, together with reasons	Describe for each group, losses and exclusions after randomisation across relevant PROGRESS-Plus characteristics, with reasons.	
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Report whether methods of recruitment were designed to reach populations across relevant PROGRESS-Plus characteristics.	
	14b	Why the trial ended or was stopped		
Baseline Data	15	A table showing baseline demographic and clinical characteristics for each group	Present the baseline characteristics also across relevant PROGRESS-Plus characteristics.	
Numbers Analyzed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups		
Outcomes and Estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)		
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended		
Ancillary Analysis	18a	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Give the results of additional analytic approaches related to equity objectives distinguishing pre-specified from exploratory.	
	18b		Details of implementation (coverage, intensity) in each trial arm	

			across relevant PROGRESS-Plus characteristics	
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Report whether intervention generated inequities (e.g. unintended effects) were assessed	
Discussion				
Limitation	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Report any limitations related to assessing effects on health equity.	
Generalizability	21	Generalisability (external validity, applicability) of the trial findings	In addition, report applicability related to population of interest across PROGRESS-Plus characteristics.	
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence		
Other Information				
Registration	23	Registration number and name of trial registry		
Protocol	24	Where the full trial protocol can be accessed, if available		
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders		