SPIRIT Checklist

Administrative information			Page number(s) where this item appears
1	TITLE	The impact of *i*-PUSH on maternal and child health outcomes, health care utilization and financial protection: a cluster randomised controlled trial based on Financial and Health Diaries data	Cover page; pp: 1
2	TRIAL REGISTRATION		
2A	2A: REGISTRY	1. NIH - ClinicalTrials.org with registration number: AfricanPHRC; Trial ID: NCT04068571 2. The American Economic Association's registry for randomized controlled trials: Trial ID: AEARCTR-0006089	Abstract; pp: 19-20
	2B: DATA SET	1. https://clinicaltrials.gov/ct2/show/NCT04068571 2. https://www.socialscienceregistry.org/trials/6089	19-20
3	PROTOCOL VERSION	Issue dates: 29 Aug 2019 and 26 Jul 2020 Protocol Amendment Number**: 01**	19-20
4	FUNDING	Dutch National Postcode Lottery, the Joep Lange Institute, and the Dutch Ministry of Foreign Affairs through the Health Insurance Fund	Funding document; 21
5	ROLES AND RESPONSIBILITIES		
	5A: CONTRIBUTORSHIP	EMS, WJ, MP and HPPD conceived the study and its design; AA, RG and CW implement the study; AN manages data; DM, SN and NM developed software for the implementation of the study.	21
	5B: SPONSOR CONTACT INFORMATION	AIGHD Foundation Tower C4 Paasheuvelweg 25 1105 BP Amsterdam The Netherlands	Funding document
	5C: SPONSOR AND FUNDER	The funder does not have any role in the design of the study and collection, analysis, and interpretation of data and in writing the manuscript.	21
	5D: COMMITTEES	The research is conducted by the independent research institutes, namely, the African	4

		Population and Health Research Center (APHRC) and Amsterdam Institute for Global Health and Development (AIGHD). These organizations and their teams manage all aspects of the trial study.	
6-8	**INTRODUCTION**		
6A	BACKGROUND AND RATIONALE	There has been a renewed international commitment to Universal Health Coverage (UHC) aiming at ensuring all people have access to the health services they need without suffering from financial hardships. Mechanism: Achieving UHC is particularly important in achieving SGDs goals related to maternal and child health (i.e., reducing the global maternal mortality ratio to less than 70 per 100 000 live births (SGD 3.1) and ending preventable deaths of newborns and children under 5 years of age (SGD 3.2). Existing knowledge: Evidence still shows that more than half of the world's population lacks access to health care of sufficient quality [1] and about 100 million people fall into extreme poverty each year due to ill-health [2], particularly in low- and middle-income countries. To translate commitment to UHC into a reality, still need to undertake systemic reforms that require strong management and organization. Need for this trial: In order to maximize the effectiveness of this program, it is important for stakeholders to have a deep understanding of current access to health services, households' health-related decision-making and out-of-pocket health care expenditures in the target populations.	3-4
6B	CHOICE OF COMPARATORS	The treatment group thus consists of the target population living in the randomly assigned 12 villages. I-PUSH roll-out in the treatment villages includes training of their CHVs with the LEAP tool, who will subsequently introduce the health wallet to eligible women living in the treatment villages, and offer them the subsidized insurance scheme on their mobile phone. The CHVs working in the control villages (as well as the remaining non-sampled villages on the longlist) will not receive training on the LEAP tool yet, nor will women in the control villages be offered the health wallet and subsidized	6

		insurance on their mobile phone. They constitute our comparison group.	
7	OBJECTIVES	To evaluate the impact of *i*-PUSH (most notably enhanced access to subsidized health insurance through the "health wallet" and increased CHV training opportunities through the LEAP training tool) on health care utilization, in particular related to maternal and child health, and financing of out-of-pocket health care expenditures.	4
8	TRIAL DESIGN	The study design is a longitudinal cluster randomized controlled trial (RCT).	5
9-15	**METHODS: PARTICIPANTS, INTERVENTIONS, OUTCOMES**		
9	STUDY SETTING	Two health clinics that were under consideration to be included in the expansion of the *i*-PUSH program. Twenty-four (24) villages located in the catchment areas of these four clinics were randomly selected from a list of all villages in the catchment areas. The list of villages was provided by the Sub-county government jointly with the *i*-PUSH program area manager. Random selection was done by the research team using a computer program to generate a short list of villages from the longlist, to be randomly assigned to either the treatment or the control group. Villages cover on average about 100 households.	5
10	ELIGIBILITY CRITERIA	The study population consists of eligible households living in the selected study villages. Eligible households included those with at least one woman of reproductive age (WRA) (18-49) who: a) had at least one child below 4 years living with her at baseline; or b) was pregnant at baseline.	7
11	INTERVENTIONS		
11a	INTERVENTIONS	*i*-PUSH is a comprehensive intervention that ultimately aims to improve the utilization of Reproductive and Maternal and Child Health (RMNCH) services among WRA and their young children in Kakamega and Nairobi Counties, by increasing knowledge about and	8

		(financial) access to RMNCH services as well as improving the quality of care of RMNCH services. In the original *i*-PUSH program that is the focus of this evaluation, households receive the first year of health insurance premium for free, and they are stimulated and supported to save for a 50% co-payment in the second year and a 100% premium payment thereafter. The free provision in year one is expected to show the benefits of insurance to the selected households. The 50% co-payment and the support for savings in the second year is expected to install a habit of savings.[1]	
11b	MODIFICATIONS	Upon on roll out of the subsidized services, eligible households are encouraged to use the services, though they are given the right to opt out at any time.	6
11c	ADHERENCE		
11d	CONCOMITANT CARE		
12	OUTCOMES	**Healthcare utilization** • Healthcare utilization for curative care (conditional on illness and/or injury): • Healthcare utilization for preventive care (immunization, growth monitoring – children below 5 only). • Continuum of maternal care (perinatal care - pregnant women only):	11-12

[1] PAF is currently working on new approaches to differentiate the size of the co-payment by socioeconomic status, which could be more effective in targeting subsidized health insurance to those who cannot afford the full premium, while at the same time, introducing new incentives to save for co-payments for those who can afford them.

		• Proportion of women who attended at least four times antenatal care during pregnancy. • Proportion of women given folic acid/iron supplementation during pregnancy. • Proportion of births attended by skilled birth attendant. • Proportion of postnatal care visits after delivery. **Health outcomes** • Proportion of children malnourished (anthropometrics). • Proportion of common childhood illnesses (e.g., diarrhoea, acute febrile illnesses, acute respiratory infections, etc.) • Proportion of women self-reporting perinatal depression. • Proportion of common mental illnesses in adults. • Proportion of other illnesses (infectious, non-communicable diseases, etc.). **Health knowledge and behavior** • Proportion of knowledge, attitude and practice to maternal and child health • Proportion of children with adequate feeding practices o Proportion of children meeting minimum meal frequency	

		○ Proportion of children meeting minimum dietary diversity • Proportion of children sleeping under a bed net **Financial protection** • Out-of-pocket healthcare expenditures • Proportion of people enrolled in NHIF • Proportion of people saving through M-TIBA • Total amount saved on M-TIBA • Proportion of people on track with savings for insurance premium on M-TIBA	
13	PARTICIPANT TIMELINE	Nov 2019 to Jun 2021	20; Appendix 1
14	SAMPLE SIZE	240 households	7-8
15	RECRUITMENT	The research team used community-level socio-demographic and infrastructure indicators from baseline data to form pairs of similar villages and determine the exact matching indicators to recruit eligible households.	5
16-17	**METHODS: ASSIGNMENT OF INTERVENTIONS (FOR CONTROLLED TRIALS)**		
16	ALLOCATION	In keeping with robustness of the cluster RCT, the procedure hence followed four steps for matching of the treatment" and "control" villages: (i) purposive selection of the Sub-county (Khwisero) where the intervention will roll out; (ii) random selection of 24 villages; (iii) pair-matching of villages based on relevant background characteristics and outcomes of interest; and (iv) randomization of treatment and control villages within each pair of the villages by flipping a coin.	5
17A	BLINDING (MASKING)	The following steps were followed: papers with paired village names were folded and put in a	6

		bag; and two village representatives from each paired village discussed on whom to pick the paper and after the other group members verified that the names could not be seen, one paper was picked. A Kenya Shilling 10 coin was used to decide which group the picked village belonged to by flipping the coin. The village representatives had decided that the head of the coin should represent the control group, justifying that Kenyatta (1st president of Kenya) was a "controlling village", and the shield to represent the intervention group. The process of choosing the folded paper and flipping of the coin was repeated for all paired villages.	
17 B	EMERGENCY UNBLINDING	N/A as there seems no unforeseen circumstances to do so.	
18-20	**METHODS: DATA COLLECTION, MANAGEMENT, ANALYSIS**		
18	DATA COLLECTION METHODS	Data collection consists of four main components: 1) a qualitative baseline study, 2) baseline and endline household surveys, 3) weekly financial and health diaries interviews with all adults and emancipated minors in the households, and 4) behavioral lab-in-the-field experiments. Both quantitative and qualitative tools were piloted in Nairobi slums and debriefed to the research team including the field team.	12
19	DATA MANAGEMENT	Trained team leaders are situated in the field to supervise real time data collection. Data quality is ensured by regular spot checks and sit-ins to approximately 5-10% of each fieldworker's daily work to verify authenticity of the data collected. Data collection is done electronically	15

		using tablets/phones, with spot checks for quality control. The field supervisors certify the quality of the data through editing the data before they are transferred to the database. Once the data collection is completed and synchronized in centrally located database, all inconsistencies are resolved prior to data analysis. An automated routine to check on the data completeness, correctness and consistency runs on 100% of the collected data. A discrepancy report is generated to help in following up on any inconsistencies or errors in the data with the responsible interviewer. Similarly, the quality of qualitative data will be ensured through recruitment and training of qualified field interviewers with experience in qualitative data collection. A qualified transcriber will transcribe the interviews verbatim and double coding of about 10% of the transcripts will also be done to ensure consistency in the application of the codes.	
20	STATISTICAL METHODS	Quantitative data will be analyzed using Stata version 14 statistical software. The first set of analysis will consist of descriptive statistics and will summarize and compare using measures of central tendency and dispersion (mean (SD), range and median). This will allow us to detect similarities and/or differences between participants' characteristics across the different sub-groups. In other words, we will compare some baseline measurements between the control and intervention groups using t-test adjusted for clustering at the village unit for continuous variables, and cluster-adjusted chi-	16

		square for binary variables. We will first check whether the outcomes and covariates in the control group and treatment group are comparable at baseline. The second set of analysis will consist assessing the causal effect of the *i*-PUSH intervention via an analysis of covariance (ANCOVA) based on intention-to-treat analysis (all respondents who are randomized will be included in the statistical analysis and will be analyzed according to the group they were initially/originally assigned). Based on our research questions, we will explore several econometric models as outlined in Appendix 1.	
21-23	**METHODS: MONITORING**		
21	DATA MONITORING		
21 A	FORMAL COMMITTEE	Data management is carried out by the research team on a progressive basis on weekly basis throughout the study duration.	15
21 B	INTERIM ANALYSIS	Interim data analyses are done using baseline and weekly diaries data.	16

22	HARM	As the information collected will be on health service delivery, financial and insurance information, we do not anticipate any risks to participants, nevertheless. We will aim to minimize the risks by being as forthcoming as possible on the project description and the ethical process. In the case of minimal discomfort as a result of personal and sensitive questions, the research team will endeavor to ensure that the participant is given ample time to compose themselves, reassure them of confidentiality and ability to stop the interview if they are not able to continue with the interview	15
23	AUDITING	Data auditing is carried out by the research team on a progressive basis on weekly basis throughout the study duration.	16
24-31	**ETHICS AND DISSEMINATION**		
24	RESEARCH ETHICS APPROVAL	The protocol was reviewed and approved by APHRC's internal ethical review committee and AMREF's accredited ethical review board. Ethical clearance was obtained on 21 April 2020 with number P679-2019. Research permits were obtained from the National Commission for Science, Technology and Innovation (NACOSTI) agency of Kenya.	16
25	PROTOCOL AMENDMENTS	Further ethical approval will be sought for any modifications to the protocol which may impact on the conduct of the study.	17
26	CONSENT OR ASSENT	Informed consent from study participants was obtained upon detail orientation on project information, the purpose of the research study, possible risks and benefits.	16
27	CONFIDENTIALITY	All interviews are conducted in privacy and no identifying information is included in any data or	16

		reports; all data is anonymized to protect the identity of respondents. The participants are given a unique code and all identification data of participants shall be shredded/destroyed after analysis has been completed.	
28	DECLARATION OF INTERESTS	All relevant information is provided under 'Declarations'.	20-21
29	ACCESS TO DATA	Access to data is granted for all research teams in respective research organizations.	15
30	ANCILLARY AND POST-TRIAL CARE	N/A as this is a community trial that does not involve any significant harm to the participating households.	16

31	DISSEMINATION POLICY	Scientific dissemination through peer-reviewed publications and implementing partners' dissemination through quarterly updates (e.g., meetings, presentations and brainstorm sessions) will ensure that findings are shared on a regular basis. These activities allow both parties to benefit from each other's insights and interpretations. Annual PharmAccess strategy meetings facilitate sharing knowledge with all country offices. Moreover, APHRC has good links with Kenyan policy makers in the field of health, and PAF is well connected to national and county-level government officials, the NHIF, as well as many local healthcare providers. Finally, the linkages between the research group, PAF and the Dutch Ministry of Foreign Affairs with respect to health financing ensure regular sharing of findings at the Dutch national policy level. The close connection of the AIGHD with the Joep Lange Institute and the Amsterdam Technology and Health Institute (ATHI) facilitates sharing of findings with parties active in social technologies (start-ups working on the interface of digital technologies and health, mobile payment platforms).	17
32-33	**APPENDICES**		
32	INFORMED CONSENT MATERIALS	Model consent form is provided in separate file.	17
33	BIOLOGICAL SPECIMENS	N/A as this is not a clinical trial.	

FIGURE. **Example template of recommended content for the schedule of enrolment,**
Figure 1. Schedule of enrolment, interventions, and assessments

	Study period			
	Enrolment	**Allocation**	**Post-allocation**	**Close-out**
	November 2019 – June 2020	**July – September 2020**	***July 2021***	***July 2021***
Enrolment:				
Eligibility screen	X			
Informed consent	X			
List other procedures	X			
Allocation		X		
Interventions:				
Intervention	X	X	X	X
Control	X	X	X	X
Assessments:				
List baseline variables	X			
List outcome variables	X			X
List other data variables	X			X

REFERENCES

[1] WHO. Tracking Universal Health Coverage: First Global Monitoring Report - World Health Organization - Google Books. 2015.

[2] Wagstaff A, Flores G, Hsu J, Smitz MF, Chepynoga K, Buisman LR, van Wilgenburg K, Eozenou P. Progress on catastrophic health spending in 133 countries: a retrospective observational study. Lancet. Glob. Heal.6:2018; e169–e179.

[3] Wangui E, Kandie C. Refocusing on quality of care and increasing demand for services: Essential elements in attaining universal health coverage in Kenya. 2016.

[4] Wehrmeister FC, Fayé CM, da Silva ICM, Amouzou A, Ferreira LZ, Jiwani SS, et al. Wealth-related inequalities in the coverage of reproductive, maternal, newborn and child health interventions in 36 countries in the African Region. Bulletin WHO. 2020; 98:394-405

[5] AMREF Health Africa.Leap, the mHealth platform [online].

[6] Imai K, King G, Nall C. The essential role of pair matching in cluster-randomized experiments, with application to the Mexican universal health insurance evaluation. Statistical Science. 2009; 24: 29-53.

[7] Hemming K, Girling AJ, Sitch AJ, Marsh J, Lilford RJ. Sample size calculations for cluster randomised controlled trials with a fixed number of clusters. BMC Med. Res. Methodol. 2011; 11.

[8] Geng X, Janssens W, Kramer B, van der List M. Health insurance, a friend in need? Impacts of formal insurance and crowding out of informal insurance. World Dev. 2018; 111:196–210.

[9] Banerjee A, Finkelstein A, Hanna R, Olken BA, Ornaghi A, Sumarto S. The challenges of universal health insurance in developing countries: Evidence from a large-scale randomized experiment in Indonesia (No. w26204). National Bureau of Economic Research. 2019.

[10] Andreoni J Sprenger C. Estimating time preferences from convex budgets," Am. Econ. Rev.2012; 102:3333–3356.

[11] KDHS. Kenya demographic and health survey: Key indicators. 2014; 1–76,

[12] United Nations Department of Economic and Social Affairs. SDGs: Sustainable development knowledge platform," United Nations. 2015.

[13] Kerber KJ, de Graft-Johnson JE, Bhutta ZA, Okong P, Starrs A, Lawn JE. Continuum of care for maternal, newborn, and child health: from slogan to service delivery. Lancet. 2007; 370:1358–1369.

[14] Okech TC, Lelegwe SL. Analysis of universal health coverage and equity on health care in Kenya. Glob. J. Health Sci. 2015; 8:218

[15] Mulupi S, Kirigia D, Chuma J. Community perceptions of health insurance and their preferred design features: Implications for the design of universal health coverage reforms in Kenya. BMC Health Serv. Res. 2013; 13.

[16] Calhoun LM, Speizer IS, Guilkey D, Bukusi E. The Effect of the removal of user fees for delivery at public health facilities on institutional delivery in urban Kenya," Matern. Child Health J. 2018; 22:409–418.