THRIFT

Transforming Households with Refraction and Innovative Financial Technology (THRIFT): A randomised controlled trial on the impact of free reading glasses to support use of smartphone banking in Bangladesh among government Old Age Allowance (OAA)/Widow Allowance (WA) beneficiaries

Statistical Analysis Plan

DOCUMENT HISTORY

Version	Date	Edited by	Comments
0.1	4 October 2022	LNS	Shared with the team for comments
0.2	11 October 2022	LNS	Updating the dummy tables
0.3	25 October 2022	LNS	Updating for consistency with the latest protocol.
1.0	5 November 2022	LNS	Approved by signatories, updated to version 1.0
1.1	24 January 2025	LNS	Adding suggestions from DMEC and TSC.
1.2	1 July 2025	LNS	Updating for consistency with the latest protocol
1.3	18 November 2025	LNS	Updating for consistency with the latest protocol. Adding adjusted analysis reporting and justification
2.0	20 November 2025	LNS	Approved by signatories, updated to version 2.0
3.0	25 January 2026	LNS	Corrected a drafting error where “number of transactions” was duplicated, and promoted value of transactions as a co-primary outcome alongside transaction count. Addition of participant versus non-participant initiated transactions in the primary outcome stratification

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ABBREVIATIONS

AE	Adverse Event
CRF	Case Report Form
CSR	Clinical Study Report
DFS	Digital Financial Services
DMEC	Data Monitoring and Ethics Committee
ITT	Intent-To-Treat
OAA	Old Age Allowance
PP	Per-Protocol
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SD	Standard Deviation
SOP	Standard Operating Procedures
TSC	Trial Steering Committee
VFQ-25	Visual Function Questionnaire-25
WA	Widow allowance

1. BACKGROUND AND DESIGN

The statistical analysis plan (SAP) for the THRIFT (Transforming Households to support use of smartphone banking in Bangladesh among government Old Age Allowance (OAA)/Widow Allowance (WA) beneficiaries through Refraction and Innovative Financial Technology) trial is presented here. The plan defines a priori the analyses that will be completed for the primary and secondary outcomes of the trial, including sub-group analyses. The plan adheres to relevant CONSORT guidelines,[1] International Conference on Harmonisation requirements[2] (ICH) and Good Clinical Practice (GCP) guidelines (E6(R1)). It has been finalised prior to unmasking of treatment allocation and is based on version 6.2 dated 14 May 2025 of the trial protocol.

The THRIFT trial is the first to examine two important determinants of mobile banking among an elderly and financially vulnerable population in a low- or middle-income country context: lack of awareness about the use of mobile banking, and uncorrected age-related decline in near vision, presbyopia. This parallel randomised trial will evaluate whether providing glasses for presbyopia and a digital financial services (DFS) training module can improve the use of mobile banking for cash transfers, deposits, and withdrawals, compared to providing these interventions after the study. The allocation sequence will be generated using a computerised randomisation system in a ratio of 1:1 for the two study groups.

The aim of the THRIFT trial is to investigate the impact of low-cost vision correction on cognitive decline in the elderly. The trial was registered under Clinical Trials Registry number NCT05510687 on 22 August 2022. The record is available at https://clinicaltrials.gov/ct2/show/NCT05510687.

2. OBJECTIVES

2.1 Primary objective

To assess whether the combined intervention of providing free eyeglasses and basic DFS training in the use of mobile phones and the THRIFT app (a module locally developed to capture digital financial transactions) to recipients of government OAA and WA safety-net payments can lead to greater financial inclusion and improved quality of life.

2.2 Secondary objectives

The study will also estimate the impact of the study interventions on secondary outcomes including: total data consumption, independent use of the mobile banking application, purchase of eyeglasses (for control group members), access to medication and healthcare, subjective well-being, mobility, social connectedness, percentage of household consumption, reasons for using or avoiding smartphone based DFS, and decision-making power within the household. These outcomes will be studied at the individual participant level; the purchase of additional phones and food security will be observed at both the participant and their household levels.

3. OUTCOME MEASURES

3.1 Primary outcome measure

THRIFT's primary outcome is the adoption and use of the DFS platform to receive digital OAA/WA transfers, as measured by the change in the average number of transactions per participant per quarter, the difference in the mean value per transaction per participant per quarter, and the difference in the mean total value of transactions per participant per quarter, comparing a 12-month period before the intervention to an 18-month period after the intervention, using transaction-level data from bKash. The analysis will be stratified by (1) WA recipients vs OAA recipients, (2) incoming vs outgoing transactions, (3) participant-initiated vs non-participant-initiated transactions, and (4) smartphone-based vs non-smartphone-based transactions (eg kiosk use).

3.2 Secondary outcome measures

- Whether use of the application was facilitated by a bKash agent or family member, or independently by the beneficiary (categorical, bKash agent or family member, or independently)
- Purchase of additional phones by study participant's household (other than by the trial participant) (binary; yes/no)
- Purchase of additional phones by study participant (binary; yes/no).
- Intra-household resource sharing by the beneficiary (as a percentage of total household consumption before and after participant starts using the app (continuous).
- Purchase of glasses other than those issued to the intervention group (binary; yes/no).
- Food security (measured using standard module developed by World Food Programme (WFP) (categorical; mild, moderate, severe).
- Role of trial participant in household decision making (continuous)
- Subjective well-being of study participant measured using then baseline survey, EQ-5D-5L and NAVQ questionnaire (continuous).
- Mobility of study participant measured using the IPAQ questionnaire (continuous).
- Social connectedness of study participant measured using the social network index (continuous).
- Self-reported incidence of theft or fraudulent use of money from the index participant's account measured using the baseline survey (binary; yes/no).
- Reasons for use/non-use of smartphone DFS (categorical)
- Assessment of depressive disorders (continuous)

4. DATA

4.1 Case Report Forms (CRFs) and variables

Full details of the data to be collected and the timing of data collection are described in the trial protocol. A copy of the CRFs and questionnaires are presented in the Trial Master File.

4.2 Management of datasets

The Data Manager will extract the data from the database. It will be stored in the LVPEI Prasad OneDrive for analysis by the Study Statistician.

4.3 Data completion schedule

CRFs and questionnaires will be completed at baseline, one month after randomisation, and five months later.

4.4 Data verification

Study specific data validation checks will be implemented. The process of data validation ensuring the accuracy and quality of the data will be carried out according to SOP Data Validation and Discrepancy Management.

5. SAMPLE SIZE CALCULATIONS

The sample size calculation allows this two-group randomised trial to have 90% power at p=0.05 to detect a 15% change (0.32 SD effect size) in the number of transactions with the app (based on data in Table 1). We assumed a drop-out rate of 15% at the follow-up survey but expect the actual rate to be much lower, based on previous work done with this population. This gives a total of 484 participants, with 242 randomly allocated to each of the intervention and control groups.

Variable of interest	**Older OAA beneficiaries**	
	Owns a phone	**Does not own a phone**
Log (Number of transactions)	1.79 (0.84)	1.56 (0.79)

Table 1: Baseline values for outcomes of interest taken from Shonchoy et al. (2021)3

6. RANDOMISATION AND BLINDING

6.1 Randomisation

Separate randomisation sequences will be prepared in advance for each of the 12 possible strata. When the baseline data have been collected for all study participants, they will be assigned in a random, replicable, computerized manner to the intervention or control group. Stratification will be based on beneficiary group (OAA/WA), age (below or above the median), gender (male/female for OAA), and previous phone use (yes/no). Age-related eligibility will vary for males and females: Old Age beneficiaries (male participants between 65 and 70 years and female participants between 62 and 70 years) and widow beneficiaries (between 48 and 60 years).

6.2 Masking and Allocation Concealment

The allocation sequence will be in a password protected location stored in designated folder for the trial by JPGSPH and will be accessed by the implementers only. The baseline data will

have the list with the allocation of the participants, and this will be shared with the implementers only. The trial will be investigator-masked, but CHWs, other fieldwork personnel and the participants will not be masked to the random assignment. This is because participants in the intervention group will receive eyeglasses at the start of the trial and members of the control group will receive eyeglasses at the end of the trial. Care will be taken to ensure that the investigators who are not involved in fieldwork will be kept masked, and we do not foresee conditions that will require emergency unmasking of them. The implementation team will receive a list of beneficiaries, and their respective group allocation based on their baseline data.

7. ANALYSIS PRINCIPLES

Primary and secondary outcomes from all randomised participants will be analysed based on the intention-to-treat (ITT) principle. That is, participants will be analysed in the group to which they were randomised regardless of whether they received the assigned treatment. Participants who withdraw consent retrospectively for the use of their data will not be included in the analyses.

It is expected that the randomisation process will minimise differences in baseline characteristics between study group. However, to increase statistical power, baseline values of continuous outcomes will be adjusted for as analysis of covariance. No formal interim analysis will be done for the primary outcome measure. All statistical tests will be at the 2-sided p-value of 0.05. A histogram and Q-Q plots will be used to test for normality and the Proportion/Chi-Square test will be used to assess proportionality. Baseline characteristics measurements will be summarised as mean and standard deviation (SD), median and inter-quartile range (IQR) or numbers and frequencies (%) as appropriate, depending on the scale of measurement and distribution (Appendix Table 1). Stata (V.18, Stata Corp, College Station, Texas, USA) and R (v.4.2.2, R Core Team) with R Studio (v.1.5.57, R Studio Team) will be used for statistical analyses.

7.1 Potential control variables

Individual and household fixed effects variables that may influence the outcomes are:

- SES indicators for the household
- Level of education of participant
- Literacy of participant
- Distance of the household from nearest bKash agent
- Distance of the household from nearest bank branch
- Distance of the household from union digital centre
- Household composition (number of adults and total number of household members)
- Economic activity of the participant

8. ANALYSIS DETAILS

The results of the analyses will be reported following the principles of the ICH E3 guidelines on the Structure and Content of Clinical Study Reports.

8.1 Recruitment and follow-up patterns

The flow of participants through each stage of screening, enrolment, randomisation and follow-up to study exit will be illustrated using a CONSORT flow diagram. Recruitment patterns will be reported by month.

8.2 Baseline Characteristics

The following baseline characteristics will be collected for each enrolled participant: age, gender, educational level, previous experience with phones, household income, other socioeconomic variables, uncorrected, presenting and corrected distance visual acuity in each eye separately and both eyes together, ownership of glasses for the correction of distance vision and self-reported regularity of use, visual function (VFQ-25), urban or rural residence, attitudes towards vision correction, access to local eye care services, history of uptake of eye care services, and household size.

8.3 Trial Outcomes

8.3.1 Analysis of primary outcome

An intention-to-treat (ITT) approach will be used to analyse the trial outcomes. This will involve regressing the outcome of concern on the randomised intervention status. The Difference in Differences (DID) for panel data will be used for analysis. The primary analysis will be stratified by (1) WA recipients vs OAA recipients, (2) incoming vs. outgoing transactions, 3) participant-initiated vs. non-participant-initiated transactions, and (4) smartphone-based vs. non-smartphone-based transactions (eg. kiosk use).

All analyses will be adjusted for age, gender, and previous phone use. Several studies with regional and rural samples have found vision problems to affect ageing populations in Bangladesh[4–6]. Previously, there has been a gender gap in eye health in Bangladesh. In 2023, Orbis, the Fred Hollows Foundation and its partners started work to close this gap[7,8].

Uncorrected vision problems have been found to negatively affect visual function, for example, smartphone and mobile phone usage among the elderly in multiple LMIC contexts 9. Random imbalances may occur hence, both the crude and adjusted estimates will be presented, but the primary inference will be based on the adjusted analysis. Both the crude and adjusted estimates will be presented, but the primary inference will be based on the adjusted analysis.

The rates of mobile banking usage, as measured in the primary outcomes, will be compared across groups of participants based on age, education, household income and other socioeconomic variables. Standard errors will be clustered at the individual level for this analysis. However, for high-frequency outcome variables (such as app-based financial transactions), data will be aggregated at the appropriate level (either monthly or weekly or quarterly), with errors clustered at the household level.

8.3.2 Sensitivity Analysis

Due to civil unrest in Bangladesh in July 2024, internet services were shut down nationally, disrupting scheduled disbursements of OAA and WA. As a result, many participants did not

receive payments for up to six months. To account for the impact of this disruption on transaction activity, sensitivity analyses will be conducted that both include and exclude transactions during the following periods: 1 May 2024 to 1 November 2024, and 1 August 2024 to 1 November 2024. These analyses will help ensure the robustness of the primary outcome by assessing whether the findings are influenced by periods of reduced financial activity linked to external events.

8.4 Analysis of secondary outcomes

8.4.1 Continuous outcomes

For continuous outcomes, we will report mean differences estimated from linear regression with identity link. All continuous outcomes will be checked for normality and appropriate transformations used. All analysis other than choice of link function will take the same form.

The continuous variables are: Intra-household resource sharing by the beneficiary (as a percentage of total household consumption before and after participant starts using the app; Subjective well-being of study participant measured using then baseline survey, EQ-5D-5L and NAVQ questionnaire; Mobility of study participant measured using the IPAQ questionnaire; Social connectedness of study participant measured using the social network index; Role of study participant in household decision making.

The quarterly transaction outcomes derived from bKash transaction level data will include: (i) number of transactions per participant per quarter, (ii) total value of transactions per participant per quarter, and (iii) mean value per transaction per participant per quarter. These outcomes will be analysed using linear mixed models to estimate quarterly outcomes over time, adjusting for potential determinants such as age, gender, educational achievement, and household size, with estimation by restricted maximum likelihood (REML). For outcomes that are skewed, appropriate transformations will be used. For total value, if values are skewed, a log transformation will be used where possible; if zeros are present, a square root transformation or alternative transformation suitable for zero values will be used. For mean value per transaction, quarters with zero transactions will be treated as missing for that outcome (as the mean value per transaction is undefined) and the analysis will be conducted among participant quarters with at least one transaction. The mean change (and its 95% CI) will be reported for 3 months versus baseline, 6 months versus baseline, 9 months versus baseline, and 12 months versus baseline. If outcomes contain many zeros, an appropriate two part or zero inflated model will be considered.

8.4.2 Binary outcomes

A binomial regression with a log-link will be used to estimate the relative risk for binary outcomes. A binomial model with identity link will be used to estimate the risk difference. In the case of non- convergence of the binomial model with a log-link, a Poisson model with robust standard errors will be fitted. If the binomial model with the identity link does not converge then only a relative risk will be reported. If neither the log or identity link converge, we will use the logistic link and report odds ratios.

The binary variables are: Purchase of additional phones by study participant's household (yes/no); Purchase of additional phones by study participant (yes/no); Purchase of glasses

other than those issued to the intervention group (yes/no); Self-reported incidence of theft or fraudulent use of money from the index participant's account measured using the baseline survey (yes/no).

8.4.3 Categorical outcomes

A multinomial logistic regression model will be used to estimate the odds ratio for the categorical outcomes. If the categories are too small; we will merge them and they will be analysed as a binary outcome (as described in section 8.4.2.2).

The categorical variables are: Whether use of the application was facilitated by a bKash agent or family member, or independently by the beneficiary (bKash agent, family member and/or independently); Food security (measured using standard module developed by WFP (mild, moderate and/or severe); and Reasons for use/non-use of smartphone DFS (categorical)

8.4.4 Health Economics

Details of the Health Economics analysis will be outlined in a separate Health Economics Analysis Plan.

8.4.5 Missing data

Every effort will be made to minimise missing baseline and outcome data in the trial due to:

Migration: Data may be missing in the event of participant migration but, considering the lower socioeconomic background of the population from which the trial participants will be drawn, migration is unlikely.

Death: Data that are not measured because of a participant's death should not be considered as missing but rather as undefined. Such data are referred to as 'truncated due to death' to distinguish them from missing data in living participants. Truncated data will be analysed differently to missing data in living participants. The proportion of attrition due to death and illness will be reported, and comparisons made of baseline characteristics of participants in the two randomised groups with observed data and missing values to assess the effect of missing data on the balance of groups for measured participant characteristics. Missing data sensitivity analyses will be conducted to explore the sensitivity of the results to different assumptions about the missingness mechanism.

Complete case analysis: If missing data is less than 5%, a complete case analysis will be done and if the data missing is more than 5%; we will employ the following procedure for imputation.

If, for each quarterly outcome data, we have at least two months data, the outcome data will be calculated based on the average of the available data points. Otherwise, multiple imputation will be done when one month data point is available. Multiple imputation will be employed if the missing data is greater than five percent and sensitivity analysis will be done to assess the results how the different imputation approaches may affect the study results.

The imputation will be carried out using MICE. The number of imputations will be determined by the proportion of missing data. The number of imputations will range between 10 and 100.

8.5 Interim analysis

No interim analysis will be done due to the nature and the short duration of the trial.

8.6 Compliance

Compliance will be assessed at two follow up visits and “collection of safety event information” by Vision Spring (one and five months after randomisation.)

8.7 Protocol deviations

Any deviations from the protocol will be presented as shown in Appendix Table 3.

8.8 Adverse events

Any adverse or serious adverse events will be recorded and presented as shown in Appendix Table 4.

9. REFERENCES

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10. SIGNATURES OF APPROVAL

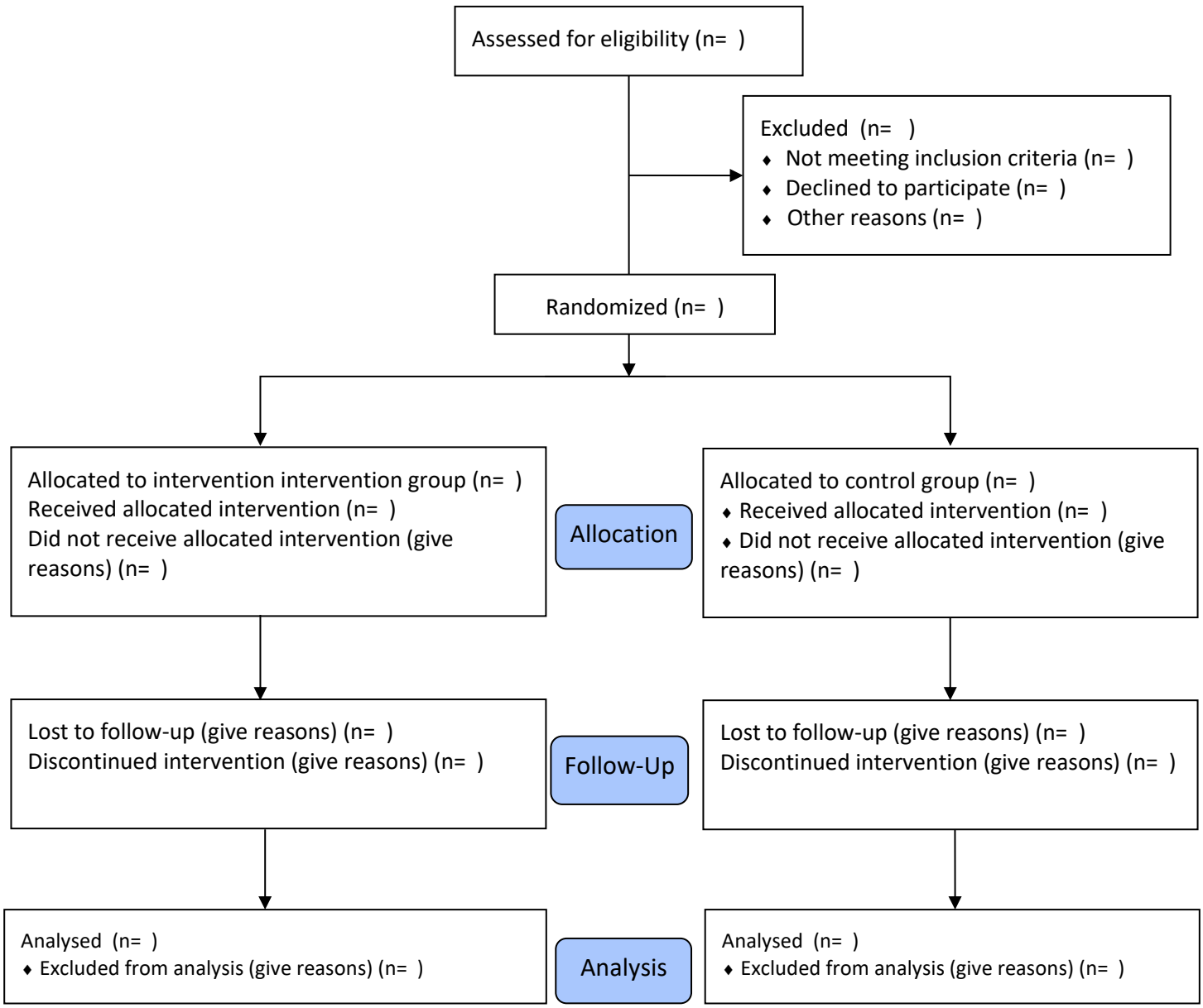
This document has completed a final review and is understood and approved by the following:

Chief Investigator Name	Chief Investigator Signature	25 Jan 2026 Date dd/mmm/yyyy

Study Statistician Name	Study Statistician Signature	25 Jan 2026 Date dd/mmm/yyyy

11. APPENDIX 1

11.1 Figure 1: CONSORT Flow Diagram1 for the THRIFT trial



11.2 Appendix Table 1: Baseline characteristics

Characteristic	**Intervention (N=)**	**Control (N=)**
DEMOGRAPHIC VARIABLE		
Gender		
Male		
Female		
Age at enrolment		
Widow allowance		
Old age allowance		
Male		
Female		
Educational level		
Never been to school/pre-school age		
Completed primary school (grade 5 pass)		
Completed secondary school certificate (SSC pass)		
Completed higher secondary school certificate (HSC pass)		
SOCIO-ECONOMIC VARIABLES		
Wealth Quintile		
Quintile 1 (-100 to -0.42)		
Quintile 2 (-0.42 to -0.36)		
Quintile 3 (-0.36 to -0.01)		
Occupation		
Employed		
Hard labour		
Domestic worker		
Unemployed		
Retired		
VISUAL FUNCTION VARIABLES		
Ownership of glasses		
Access to local eye care services		
History of eye care services uptake		
HOUSEHOLD SIZE		

Mean (SD) or median and interquartile range, where appropriate, are presented for continuous variables and number (%) for categorical variables.

11.3 Appendix Table 2: Effects of the intervention

Primary Outcome		**Int (N=)**	**Cont (N=)**	**Effect estimate**
Change in the average number of transactions per participant per quarter, comparing a 12-month period before the intervention to a 18-month period after the intervention: WA recipients OAA recipients Incoming transactions Outgoing transactions Smart-phone based Non-smart-phone Participant initiated Non-participant initiated	Mean (SD)			Mean difference (95% CI)
Change in the difference in the mean value per transaction per participant per quarter, comparing a 12-month period before the intervention to a 18-month period after the intervention: WA recipients OAA recipients Incoming transactions Outgoing transactions Smart-phone based Non-smart-phone Participant initiated Non-participant initiated	Mean (SD)			Mean difference (95% CI)
Change in the difference in the mean total value of transactions per participant per quarter, comparing a 12-month period before the intervention to a 18-month period after the intervention: WA recipients OAA recipients Incoming transactions Outgoing transactions Smart-phone based Non-smart-phone Participant initiated Non-participant initiated	Mean (SD)			Mean difference (95% CI)
Secondary Outcomes				
Intra-household resource sharing by the beneficiary (as a percentage of total household consumption before and after participant starts using the app.	Mean (SD)			Mean difference (95% CI)
Subjective well-being of study participant measured using the baseline survey, EQ-5D-5L and NAVQ questionnaire	Mean (SD)			Mean difference (95% CI)
Mobility of study participant measured using the IPAQ questionnaire	Mean (SD)			Mean difference (95% CI)

Social connectedness of study participant measured using the social network index	Mean (SD)			Mean difference (95% CI)
Role of study participant in household decision making	Mean (SD)			Mean difference (95% CI)
Application use bKash agent Family member Independent	n (%)			Proportion difference (95% CI)
				Odds ratio (95% CI)
Purchase of additional phones by trial participant's household No Yes	n (%)			Proportion difference (95% CI)
				Odds ratio (95% CI)
Purchase of additional phones by trial participant No Yes	n (%)			Proportion difference (95% CI)
				Odds ratio (95% CI)
Purchase of glasses other than those issued to the intervention group No Yes	n (%)			Proportion difference (95% CI)
				Odds ratio (95% CI)
Food security (measured using standard module developed by WFP) Mild Moderate Severe	n (%)			Proportion difference (95% CI)
				Risk ratio (95% CI)
Self-reported incidence of theft or fraudulent use of money from the index participant's account measured using the baseline survey No Yes	n (%)			Proportion difference (95% CI)
				Risk ratio (95% CI)
Reasons for use/non-use of smartphone DFS	n (%)			
Depressive symptoms of study participant (PHQ 9)	Mean (SD)			Mean difference (95% CI)

11.4 Appendix Table 3: Protocol Deviations

	Number of events			Number of participants		
	Total	**Intervention**	**Control**	**Total (N=)**	**Intervention (N=)**	**Control (N=)**
Eligibility						
Consent						
Study Intervention Administration						
SAE reporting timelines						
Visit outside schedule						
Other						

Number (%) presented by randomised group for categorical variables.

11.5 Appendix Table 4: Adverse Events

	Number of events			Number of participants				
	Total	**Int**	**Cont**	**Total (N=)**	**Int (N=)**	**Cont (N=)**	**RR (95%CI)**	**p-value**
Adverse events								
Adverse reactions								
Unexpected adverse reactions								
Serious adverse events								
Serious adverse reactions								
Suspected unexpected serious adverse reactions								
Fatal serious adverse events								

Number (%) presented by randomised group for categorical variables and relative risk (95% CI).