

Statistical Analysis Plan

STUDY TITLE	Improving access to family planning (IFPLAN) for women with disabilities in Kaduna city, Nigeria: A pragmatic cluster-randomized controlled trial
SAP VERSION	1.4
SAP VERSION DATE	15 September 2026
INVESTIGATORS	London School of Hygiene and Tropical Medicine: Hannah Kuper (co-PI) Sarah Marks (co-I) Christian Bottomley (Statistician) Mark T. Carew (co-I) Oxford Policy Management: Ekundayo Arogundade (co-I) Saviour Kolo (co-I) Babatunde Akano (co-I) Stanley Nyoro Gichiri (Analyst) Femi Adegoke (co-I) Sylvia Blom (Statistician)
FUNDER	United Kingdom Foreign, Commonwealth and Development Office (FCDO)
SPONSOR	London School of Hygiene and Tropical Medicine
SAP AUTHOR	Sylvia Blom, Sarah Marks, Christian Bottomley

Table of Contents

Abbreviations	3
Introduction	4
<i>Background</i>	<i>4</i>
<i>Study Objectives.....</i>	<i>4</i>
Study Design	4
<i>Overview</i>	<i>4</i>
<i>Intervention.....</i>	<i>5</i>
<i>Health Facility Selection</i>	<i>7</i>
<i>Recruitment</i>	<i>7</i>
<i>Inclusion-Exclusion Criteria.....</i>	<i>7</i>
<i>Randomisation and Blinding</i>	<i>7</i>
<i>Sample Size</i>	<i>8</i>
Data Storage	9
Analysis Cohort	10
Study Variables.....	10
Interim Analyses and Timing of Final Analysis.....	15
Subgroup Analyses	15
Statistical Considerations.....	15
<i>Balance test and descriptive analysis of participants</i>	<i>15</i>
<i>Characteristics of the Intervention</i>	<i>16</i>
<i>Effectiveness analysis.....</i>	<i>16</i>
<i>Missing Data.....</i>	<i>17</i>
<i>Sensitivity Analysis</i>	<i>17</i>
<i>Exploratory Analysis</i>	<i>18</i>
<i>Multiple Testing</i>	<i>18</i>
<i>Statistical Software</i>	<i>18</i>
References.....	18
Dummy Tables	19

Abbreviations

CI	Confidence Interval
DHS	Demographic and Health Surveys
DISC	Disability Inclusive Scorecard
IFPLAN	Inclusive Family Planning
IRR	Incidence rate ratio
LTFU	Lost to follow-up
OPDs	Organizations of persons with disabilities
OR	Odds Ratio
PPI	Poverty probability index
SBC	Social and behaviour change
SRHR	Sexual and reproductive health and rights

Introduction

Background

Nigeria has 54 million women of reproductive age (15–49 years). Amongst women in this age group, 0.6% were reported in the 2018 Demographic Health Survey (DHS) to have a disability. This figure does not include any type of psychosocial disability, such as depression or anxiety. The met need for family planning was almost 10 percentage points higher amongst women without disabilities (28%) than for women with disabilities (19%). Identified barriers to accessing reproductive health services amongst women with disabilities in Nigeria, include significantly lower awareness of family planning, as well as impairment-specific barriers.

To help address these disparities, an inclusive sexual and reproductive health project has been designed and delivered by a consortium led by the international non-governmental organization Sightsavers, supported by BBC Media Action under the Disability Inclusive Development programme, and in partnership with the Joint National Association of Persons with Disability and the Network of Disabled Women in Nigeria. The Inclusive Family Planning (IFPLAN) project aims to increase access to modern contraceptive methods and reduce unmet need for family planning for women with disabilities aged 15–49 years in Kaduna city, Nigeria. The project's objectives include increasing knowledge of, intention to use, and perceived support amongst women with disabilities in accessing available family planning services; delivery of inclusive, accessible healthcare services and information by service providers; and meaningful engagement of organizations of persons with disabilities (OPDs) in policy and decision-making processes, and advocacy for disability inclusion in the health sector.

Study Objectives

This trial aims to answer the following research questions:

- (1) Did the intervention increase access to family planning amongst women with disabilities in selected sites in Kaduna city?
- (2) Did the intervention increase use of family-planning services amongst women with disabilities in selected sites in Kaduna city?
- (3) Did the intervention reduce the unmet need for family-planning services amongst women with disabilities in selected sites in Kaduna city?

Study Design

Overview

A pragmatic cluster-randomized controlled superiority trial with integrated process evaluation has been designed to assess the impact of the package of IFPLAN interventions on family planning outcomes.

In this study, clusters are defined as health facilities or clusters of health facilities with the same catchment areas in and around Kaduna City, Kaduna State, Nigeria. Public and private health facilities providing primary, secondary, and tertiary care were eligible for

inclusion in the sample so long as they provided family planning services to the general public. Health facilities were removed from the sample if they were in areas that were too insecure for data collection. To reduce the likelihood of contamination across sites, selected health facilities were removed from the sample such that the remaining sample of health facilities (n=37) were at least 0.5 km apart.

Health facility catchment areas were randomised into one of two study arms: the intervention arm which received the IFPLAN package of interventions and the control arm, which received 'standard' provision of family planning services in the state, in the context of state-wide and national broadcast media and advocacy conducted by IFPLAN.

Within each catchment area, women of reproductive age (18-49 years) with a disability (classification based on the Washington Group questionnaire) were recruited for the study using a house-to-house survey. In addition, a neighbourhood matched sample of women of reproductive age without a disability were recruited for the study.

The primary outcome for the trial is access to modern family-planning methods. Secondary outcomes include knowledge of modern contraceptive methods, use of (modern method) family planning, demand for family planning, intention to use, unmet need for family planning, participation/inclusion of women with disabilities and perceived attitudes toward women with disabilities.

Baseline data was collected December 2022 to January 2023. The intervention was implemented from April 2023 to October 2025. Endline data was collected December 2025 to March 2026 (see timeline below).

Table 1 IFPLAN evaluation timeline

	2022			2023				2024				2025				2026			
Quarter	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Ethics																			
Baseline																			
Implementation																			
Process Evaluation																			
Endline																			
Analysis																			
Write-up and Dissemination																			

Intervention

The IFPLAN project aims to address multiple barriers to inclusion in family-planning services, using adaptive management and data to target and adjust programme components. The project comprises a range of national, state, and community and facility-based interventions of which this trial will only evaluate the community and facility-based interventions.

Intervention activities are designed to improve family planning by improving demand (pathway 1), supply (pathway 2), or structural issues (pathway 3).

Pathway 1

Pathway 1 is informed by a social and behaviour change (SBC) strategy to support people with disabilities to feel able, confident, motivated and supported if and when they choose to use modern contraceptives and practice family planning/ child spacing. The SBC activities include a weekly Hausa language radio drama, complemented by accessible digital and social media content, as well as interpersonal communication activities at the community level. These community-level activities include structured peer-to-peer sessions for people with disabilities to increase knowledge on sexual and reproductive health and rights (SRHR) and confidence in overcoming barriers to use services, if and when they need them, based on their own informed choices and bodily autonomy; household visits by Dilalyas to spread disability-inclusive family planning messages; family planning board game played by Majalisas, existing community assemblies of male heads of households in Northern Nigeria to gain their engagement and support; town hall meetings to gain engagement and support from local leaders; and community plays to educate on SRHR and build on the stories from the radio drama.

Pathway 2

Pathway 2 supply-side activities are all implemented at the health facility level and include: (1) participatory score card assessments of primary healthcare facilities conducted by people with disabilities, service providers and decision-makers using Sightsavers' Disability Inclusive Scorecard (DISC) tool; (2) disability inclusive training of service providers; and (3) accessibility audits of and improvements to family planning facilities.

Pathway 3

To support structural changes under pathway 3, activities focused around capacity building of OPDs, advocacy for inclusive SRHR, and representation of OPDs in healthcare committees. These activities were implemented at the state or regional level and hence not evaluated as part of this trial as they will impact both treatment and control arms.

To summarize, the community-level activities that will be evaluated through this trial include the interpersonal communication activities in pathway 1 (peer-to-peer sessions, Dilalya visits, Majalisa board game, community plays and town hall meetings) and all of the supply-side activities in pathway 2 (participatory scorecards, health facility worker training, accessibility audits and improvements).

Duration of implementation

30 months

Phases of implementation

The intervention activities were implemented in two phases by Sightsavers. The sequencing and timing of activities was simply due to funding constraints of the implementing partner, as opposed to a theory-driven approach.

Health Facility Selection

Health facilities were included in the study if they were functioning health facilities that provide family planning services to the general public. Health facilities could be public or private and provide primary, secondary, or tertiary care. Military and air force facilities were excluded as they were not open to the general public. Health facilities in insecure areas where data collection could not take place safely were also excluded.

To reduce contamination, we then mapped the health facility catchment areas (defined as the area within a 0.5 km radius of the facility location) and grouped together facilities with the same catchment area (defined as being less than 0.5km apart). We then identified the smallest number of health facilities that, when removed would leave the remaining health facilities with at least a 0.5km buffer between catchment areas. We then removed these facilities, leaving a sample of 37 health facility catchment areas.

Recruitment

Female enumerators conducted a house-to-house survey to find women in the included age range. Those women were asked the Washington Group enhanced set of questions (with the exception of questions on upper body strength as local partners felt that “raising a 2 liter bottle of water or soda” would not be well understood by participants). Those who were identified as having a disability based on these questions were asked to enroll in the study. They were asked further questions covering their sociodemographics and the primary and secondary outcomes.

A neighborhood-matched sample of women without disabilities was also interviewed for each woman with disabilities included in the sample; these were recruited as the next woman aged within +/- 5 years, without disabilities, who consented to take part in the study. If there were no more women in the neighbourhood, the survey team selected a woman without disabilities at random from the women previously screened.

Inclusion-Exclusion Criteria

Women were recruited if they met the following inclusion criteria:

1. People who identify as women, aged 18-49 years at baseline (in this context we do not expect to find any trans men)
2. For women with disabilities, they must report at least ‘a lot’ of difficulty on at least one of the six questions in the Washington Group short set or ‘daily’ and ‘a lot’ to the enhanced questions on depression or anxiety
3. For women without disabilities, they must be from the same cluster and aged within +/-5 years of the woman with disabilities

Participants were excluded if they were not able to consent on their own.

Randomisation and Blinding

Randomisation

Health facility catchment areas were randomized to a study arm using blocked randomization. The first 19 clusters drawn were allocated to the intervention arm and the remaining 18 clusters allocated to the control arm.

Cluster allocation was conducted through a random draw conducted by government officials in Kaduna during a multi-stakeholder event organised by Sightsavers. Cluster numbers were hidden during allocation using concealed cards.

Blinding

Due to the nature of the intervention, it was not possible to blind facilities/participants to the intervention after assignment.

Sample Size

The healthcare facility catchment area selection process resulted in a sample size of 37 healthcare facilities (19 intervention; 18 control). This is one fewer than the intended size of 38 healthcare facility catchment areas, upon which the original sample size calculations were based.

Sample-size calculations were guided by the number of areas that the implementing partner, Sightsavers, had capacity and funding to reach. Security considerations limited implementation to Kaduna city. The target population was women aged 18–49 years with disabilities, consistent with the protocol definition of women of reproductive age (15–49 years), excluding those under 18 as this is the age of legal majority and the minimum age for independent informed consent in Nigeria. These women were matched with a sample of women without disabilities.

We used Excel to calculate the size of the target population (women 18–49 years with disabilities) in each catchment area. Sample size calculations were based on the approach proposed in Hayes and Bennett (1999) for cluster-randomised controlled trials. The assumptions, as summarized in Table 1, were used in determining the likely number of women 18–49 years with disabilities living in the catchment areas. There was limited context-specific evidence available to inform these assumptions. Therefore, values were based on the best available data and informed judgement, and were discussed and agreed with the implementing partner prior to use.

Table 1: Assumed and derived values for the IFPLAN cluster randomized controlled trial sample size calculations

Assumptions:	
Proportion of women aged 18–49 years	20.0%
Proportion of women 18–49 years who are disabled based on Washington Group Questions ^a	0.7%

Proportion of women 18–49 years with depression or anxiety ^b	6.0%
Estimated overlap between the above	30%
Number of people in each cluster	10,000
Proportion of women who have 'access' to family planning	25%
Derived values:	
Number of women aged 18–49 years (10,000 × 20%)	2000
Proportion of women 18–49 years who are disabled overall (6% + (0.7% × (100–30%)))	6.49%
Number of women 18–49 years who are disabled (2000 × 6.49%)	130

^aThis is women who report 'a lot of difficulty' or 'cannot do at all' to one of the six domains in the Washington Group Short Set of questions, with this prevalence found in the DHS 2018 data for women 18 to 49 years old in Nigeria

^bThis is the proportion of women who report depression or anxiety using the questions from the Washington Group Enhanced set of questions. This value is based on research in Lagos, in the south of Nigeria [1]

Various options, in terms of the number and size of the clusters, were explored. The preferred option is highlighted in bold in table 2.

1-type I	power	Access in cont. arm	Risk ratio	Access in treat. arm	Clus. size	k	Clus. in arm	Total Clus.	Total N	Total HHs screened
0.95	0.8	25%	1.5	37.5%	130	0.3	12	24	3,115	60,000
0.95	0.8	25%	1.5	37.5%	50	0.3	15	30	1,500	28,891
0.95	0.8	25%	1.5	37.5%	25	0.3	19	38	950	18,297

Assuming the between-cluster coefficient of variation (k) to be 0.3, a baseline level of family planning access of 25%, a 5% significance level, and 80% power, the trial can detect a risk ratio of 1.5 (*i.e.* a 50% increase in access compared to the control arm) with 25 women with disabilities interviewed in each cluster. This yields a sample of 925 women with disabilities and 925 women without disabilities for 37 clusters. This sample size requires approximately 20,000 households to be screened for eligible women.

Data Storage

Data entry for the baseline and endline surveys was conducted electronically using tablets, with digital forms programmed using SurveyCTO, replicating the paper forms approved by

the Institutional Review Boards. Validation and consistency checks were programmed into the data collection forms and applied at the point of data entry into a specific field. Collected data is password protected on devices and servers.

Analysis Cohort

The analysis cohort will consist of women with and without disabilities who were interviewed at endline.

At endline, every effort will be made to follow-up with women surveyed at baseline. Participants that cannot be reached will be noted. If the participant has moved away, the team will try follow up via phone survey. For participants followed up by phone, a shortened questionnaire will be administered containing the items required to construct the primary outcome. Telephone respondents will contribute to secondary outcomes only where all items required to construct that outcome were included in the telephone questionnaire. If the proportion of participants that are lost to follow-up (LTFU) within the cluster exceeds 10% then women will be recruited at endline as replacements using the same criteria as at baseline.

Upon review of the baseline data, we found that some observations had been mislabeled as cluster 37, where instead they were cluster 36. Therefore no participants in cluster 37 were identified at baseline. In order to achieve our intended cluster sample we will therefore recruit women in this cluster at endline using the same criteria as at baseline. This will be acknowledged in the analysis and write-up of the trial.

Women recruited at endline will need to meet the original eligibility criteria plus residence in their respective cluster of at least three years. Note that the age restriction will be based on participants' age when the baseline survey occurred.

The additional recruitment in clusters where the LTFU rates exceeds 10% and the additional recruitment of women in cluster 37 is to ensure an adequate sample size at endline. However, this means baseline variables cannot be adjusted for in the endline analysis for these women. As such, the primary analysis will compare treatment and control groups at endline, without baseline controls.

To test the effect of the intervention on women with and without disability, analyses will be initially conducted separately for each group. To determine whether the intervention effects differ between women with and without disability, combined data will be analysed with an interaction term between intervention arm (yes or no) and disability status (yes or no) included in the statistical model.

Study Variables

Primary outcome: Access to family planning

Access to family planning will be defined as a binary variable measured at endline. A participant will be classified as having access (coded 1) if all the following conditions are met:

- (1) Know of at least three modern contraceptive methods that are available;
- (2) Know where to access modern family-planning *and* name the location *and* list the available family planning services; and
- (3) Believe that they could use services if they needed them

Participants who do not meet all three criteria will be classified as not having access to family planning (coded as 0).

The denominator is *all women who complete the endline survey*, including women followed up via telephone interview.

Details on outcome construction:

- (1) Know of at least three modern contraceptive methods that are available. Modern methods include: female sterilization, male sterilization, IUD, injectable, implant, pill, male condom, female condom, emergency contraception, standard days method, and lactational amenorrhea method (LAM) [q301a-q301k]. Traditional methods include: rhythm method and withdrawal. Responses to the open-text “other method” item (q301n/q301_oth) will not contribute to the count of modern methods known.
- (2) Know where to access modern family-planning *and* name the location *and* list the available family planning services: Participant says they know where to access family planning [q326] AND names one of the health facilities in the trial OR can provide a specific name of another health facility (which is known to the enumerator) [q326a] AND can indicate an approximate amount of time it would take to travel there (regardless of whether correct) [q326ai] AND can list at least one modern family planning method available at that centre (regardless of whether it is actually offered there, and with no penalty for also listing a traditional method) [q326b]
- (3) Believe that they could use services if they needed them: Participant does not think any of the following factors are a “big problem” when accessing healthcare: Getting permission, getting money, distance, attitude of healthcare workers, accessibility of health facility, or lack of information [q1108a-c; q1108e-h]

Secondary outcomes

- **Knowledge of three or more modern family planning methods:**
 - See definition above.
 - Denominator: All women (including women that completed the telephone survey). Women for whom missing responses prevent determination of whether at least three methods are known will be treated as missing for this outcome.
 - Binary outcome
- **Current use of modern contraception:**
 - Women who are (or whose partner’s are) currently using a modern contraceptive method to delay or avoid pregnancy.
 - Numerator: Current modern contraceptive use will be derived using female sterilisation status [q801], current pregnancy status [q802], current contraceptive use [q807] and method(s) currently used [q304]. Women will be

classified as current modern contraceptive users if q801=1 (woman reports being sterilised), or if q807=1 and q304 includes at least one modern method. Modern methods are q304 codes 1–11 and 14: female sterilisation, male sterilisation, IUD, injectable, implant, pill, male condom, female condom, emergency contraception, standard days method, LAM, and other modern method. Women reporting q807=0, or q807=1 but reporting only traditional methods [q304 codes 12, 13 or 15: rhythm, withdrawal or other traditional method], will be coded 0. Women who are currently pregnant [q802=1] will be coded 0 for current contraceptive use as pregnant women are not currently using contraception to delay or avoid pregnancy.

- Denominator: Women who are married/in union [q701=1 or q701=2]. Participants with missing data on current marital/union status or current contraceptive use will be excluded from the analysis for this outcome.
 - Binary outcome
 - **Unmet need for family planning:**
 - Number of women with an unmet need for family planning for spacing or limiting births.
 - Numerator: Women currently using any contraceptive method will be classified as not having unmet need. Current contraceptive use will be identified from q801 and q807: women reporting female sterilisation (q801=1) or current use of any contraceptive method (q807=1), whether modern or traditional, will be coded as having no unmet need. Among women who are **not currently pregnant** (q802=0) and are not currently using contraception (q807=0):
 - **Unmet need for spacing** will be assigned if the woman wants a/another child (q804=1) and wants to wait at least 24 months before the birth of that child (q805a $\geq$ 24 months); wants another child but is undecided about the timing of the next child; or is undecided whether she wants another child (q804=-98). Responses that are genuinely missing, rather than indicating uncertainty about fertility preferences or timing, will be treated as missing for the unmet-need outcome.
 - **Unmet need for limiting** will be assigned if the woman reports that she wants no more/no children (q804=2).
 - Women who want a/another child within the next 24 months (q804=1 and q805a < 24 months) will be classified as having no unmet need.
 - Women who report that they cannot become pregnant (q804=3) will be classified as not having unmet need¹
- Among women who are **currently pregnant** (q802=1), wantedness of the current pregnancy will be determined using q228 and q229a/q229b:
- women who report that they wanted to become pregnant at the time the current pregnancy occurred (q228=1) will be classified as having no unmet need;

¹ The IFPLAN questionnaire does not contain the full DHS classification of postpartum amenorrhoea and infecundity that are used to produce the DHS unmet-need variable.

- women who report that they did not want to become pregnant at that time (q228=0) and report that they wanted a baby later (q229a=1 or q229b=1, as applicable) will be classified as having **unmet need for spacing**;
- women who report that they did not want to become pregnant at that time (q228=0) and report that they wanted no more/no children (q229a=2 or q229b=2, as applicable) will be classified as having **unmet need for limiting**.

Total unmet need will be coded 1 for women meeting the criteria for either unmet need for spacing or unmet need for limiting, and 0 otherwise.

- Denominator: All women in the endline analysis cohort who report that they are currently married (q701=1) or living with a man as if married (q701=2), including women who are currently pregnant (q802=1) and women who report that they have been sterilised (q801=1). Sterilised women remain in the denominator but, because they are using contraception, will be classified as not having unmet need. Pregnant women remain in the denominator and will be classified using the wantedness of the current pregnancy (q228 and q229a/q229b), as described above. Participants for whom the information required to determine unmet-need status is missing will be treated as missing for this outcome.
- Binary outcome
- **Demand for family planning:**
 - Women who either 1) are currently using any contraceptive method (modern or traditional – including sterilisation) or 2) have unmet need for family planning for spacing or limiting.
 - Numerator: Women will be classified as having demand for family planning if they are currently using any contraceptive method (modern or traditional, including sterilisation) or are classified as having unmet need for family planning for spacing or limiting, according to the definition above. Current contraceptive use will be identified using q801 and q807. Women reporting female sterilisation (q801=1) or current use of any contraceptive method (q807=1) will be classified as current contraceptive users. Women meeting neither the current-use nor unmet-need criterion will be coded 0.
 - Denominator: All women in the endline analysis cohort who report that they are currently married (q701=1) or living with a man as if married (q701=2). Women who are sterilised will remain in the denominator and will be classified as having demand through current contraceptive use. Women who meet neither the current-use nor unmet-need criterion will be coded 0. Participants for whom demand cannot be determined because the information required to establish both contraceptive-use and unmet-need status is missing will be treated as missing.
 - Binary outcome
- **Intention to use:**
 - Women that are not currently using contraception who report they will use a contraceptive method in the future to delay or avoid pregnancy.

- Numerator: Women answering “yes” to q812 (q812=1) will be coded 1 and women answering “no” (q812=0) will be coded 0. A “don’t know” response (q812=-98) will be treated as missing for this outcome.
- Denominator: Women in the endline analysis cohort who are currently married (q701=1) or living with a man as if married (q701=2), have not been sterilised (q801=0), and are not currently using any contraception (modern or traditional (q807=0). Participants with missing information required to establish denominator eligibility or with q812=-98 will be treated as missing for this outcome and excluded from the analysis.
- Binary outcome
- **Perceived inclusion/participation among women with disabilities:**
 - Perceived inclusion/participation will be assessed among women with disabilities using the eight items q41a–q41e, q41g, q41h and q41j. These items assess participation and inclusion within the household, family and wider community.
 - Score derivation: Responses to each included item will be coded so that higher values indicate greater perceived inclusion/participation and will be placed on a common 0–2 scale. For q41a, responses will be scored 0 for “No”, 1 for “Sometimes” and 2 for “Yes”. For the binary items q41b–q41e, q41g, q41h and q41j, responses will be scored 0 for “No” and 2 for “Yes”. “Don’t know” and other non-substantive responses will be treated as missing. The inclusion/participation score will be calculated as the mean of the available included item scores and transformed to a 0–100 scale as: $(\text{mean item score} / 2) \times 100$, with higher scores indicating greater perceived inclusion/participation. The score will be calculated for women with valid responses to at least 6 of the 8 included items. Where fewer than 6 items have valid responses, the score will be treated as missing.
 - Denominator: Women with disabilities in the endline analysis cohort.
 - Continuous outcome
- **Perceived attitudes toward women with disabilities:**
 - Perceived attitudes will be assessed using the nine items q42a–q42i.
 - Score derivation: Each item is measured on a five-point scale from 1 (“Strongly disagree”) to 5 (“Strongly agree”). Items will be oriented so that higher scores consistently indicate more positive perceived attitudes.
 - q42c, q42d and q42e are positively worded and will retain their original coding (1–5).
 - q42a, q42b and q42f–q42i are negatively worded and will be reverse-scored as 1→5, 2→4, 3→3, 4→2 and 5→1.
 - “Don’t know” and other non-substantive responses will be treated as missing.

The perceived-attitudes score will be calculated as the mean of the available included item scores and transformed to a 0–100 scale as: $((\text{mean item score} - 1) / 4) \times 100$, with higher scores indicating more positive perceived attitudes. The score will be calculated for women with valid responses to at least 7 of the 9 included items. Where fewer than 7 items have valid responses, the score will be treated as missing.

- Denominator: Women with disabilities in the endline analysis cohort.
- Continuous outcome

Interim Analyses and Timing of Final Analysis

There is no interim analysis. Final analysis will take place after the endline (2026).

Subgroup Analyses

Analyses will be presented separately for women with disabilities and women without disabilities, as described under Effectiveness Analysis.

One prespecified subgroup analysis will be conducted for the primary outcome among women with disabilities, in accordance with the trial protocol. This analysis will be restricted to women who met the disability eligibility criteria through at least one functional difficulty other than anxiety or depression. Women with anxiety or depression in addition to another qualifying functional difficulty will remain eligible for this subgroup. Women whose disability classification was based only on anxiety and/or depression will be excluded from this subgroup analysis.

No other subgroup analyses are prespecified.

Statistical Considerations

Balance test and descriptive analysis of participants

We will present a flow diagram that shows the numbers of women surveyed (and clusters) at baseline and endline by trial arm, and the number of women included in the main analysis cohort.

We will provide descriptive statistics and assess balance across study arms for the women with and without disabilities separately.

As described earlier, due to the need for additional recruitment at endline, there will be a subset (expected to be 5-15%) of participants for whom we do not have full baseline data. As such, for the full group of endline participants, we will compare balance across time-invariant characteristics. For time-varying characteristics we will present data at baseline where available at endline. We note that time-varying characteristics measured at endline may be affected by the intervention.

Time-invariant characteristics to be compared for all participants as reported at endline:

- Age group
- Ethnicity

- Religion
- Highest Level of Education Attended
- Literacy
- Wealth quintile (derived from the poverty probability index score and categorised into quintiles based on the distribution of PPI scores among all women in the endline sample).

Time-varying characteristics to be reported at baseline and endline.

- Marital status (Married or in union/other)
- Ever had sex (Y/N)
- Watch TV (At least once a week/less than once a week)
- Own a mobile phone (Y/N)
- Ever used internet (Y/N)
- Number of live births

For the women with disabilities, we will also report the proportion of women with different impairment types at recruitment (vision/hearing/mobility/communication/cognition/selfcare/anxiety/depression). Categories are not mutually exclusive; women may have more than one type of form of impairment. Therefore we will also report the proportion of women with more than one impairment type.

Characteristics of the Intervention

The description of the intervention will adhere to the TIDieR guidelines [TIDieR Checklist](#).

Participants' self-reported exposure to IFPLAN intervention components will be summarised descriptively by randomized trial arm and disability status for both the past 12 months and the three-year intervention period. The 12-month recall period provides a measure of more recent intervention exposure, while the three-year recall period captures reported exposure over the approximate duration of intervention implementation. Responses to the placebo intervention item ("IFPLAN Connect") will also be summarised descriptively as an indicator of potential over-reporting of intervention exposure.

Effectiveness analysis

The effect of the intervention will be estimated with a multi-variable regression model, in which the specific model will depend on the type of outcome. All models will be comparisons of endline outcomes between trial arms. All models will include a random effect for cluster to account for clustering of observations and fixed effects for local government area (LGA) to account for geographic variation. We will report unadjusted and adjusted analyses for all outcomes. Adjusted analyses will include age group and educational attainment as prespecified individual-level covariates, selected because they are expected to be prognostic of family planning outcomes and are unlikely to have been affected by the intervention.

Covariates will not be selected for inclusion based on statistical tests or observed differences between trial arms.

We will first report analyses for women with and without disabilities separately. Then, we will pool the samples, and include an interaction term between trial arm (intervention vs control) and disability status (yes vs no) in the statistical model to assess whether there is a differential effect of the intervention for women with disabilities.

Primary and Secondary outcomes (family planning)

The family planning outcomes are binary variables. These will be analysed using multilevel binomial regression models with a log link to estimate adjusted risk ratios (aRRs) and 95% confidence intervals.

Secondary outcomes (disability inclusion)

Perceived inclusion/participation and perceived attitudes toward women with disabilities are separate continuous secondary outcomes, each scored from 0 to 100 as defined above. Each outcome will be analysed separately using a multilevel linear regression model to compare intervention and control arms, with a random effect for cluster and the same prespecified adjustment variables as the primary effectiveness analysis. Analyses of these outcomes will be restricted to women with disabilities.

Missing Data

Missing outcome data

An available-case approach will be used for missing outcome data. For each outcome, participants will be included where the available questionnaire responses are sufficient to determine the outcome according to the definitions specified above. Participants for whom missing responses prevent determination of the outcome will be treated as missing for that outcome and excluded from its analysis.

Missing covariate data

Adjusted analyses will use a complete-case approach with respect to the prespecified adjustment covariates, age group and educational attainment. Participants with missing data on either adjustment covariate will be excluded from the adjusted analysis. We expect missingness in these covariates to be minimal.

Missing data on baseline outcome

The primary analysis will compare outcomes between study arms at endline without adjustment for the baseline outcome. This is because there is extensive missingness in the baseline outcome resulting from questionnaire skip-logic errors, and baseline outcome data are unavailable for participants recruited as replacements at endline.

Sensitivity Analysis

Sensitivity analysis will be conducted for the primary outcome amongst women with disabilities only (as this is the main population of interest) and comprise:

Sensitivity analysis 1: Baseline-Endline Cohort

The main analysis cohort includes all participants interviewed at endline, including replacement participants for whom baseline data are unavailable. Thus the first sensitivity analysis will assess effectiveness using the cohort of participants observed at both baseline and endline (the baseline-endline cohort), to examine the impact of including replacement participants in the main analysis.

Sensitivity analysis 2: Exclusion of Telephone Interviews

In the main analysis, participants followed up by phone at endline are included. As outcome reporting may differ between in-person and phone-based interviews, the second sensitivity analysis will exclude participants interviewed by phone at endline to assess the robustness of the findings to mode of data collection.

Exploratory Analysis

Given anticipated variation in the reach and implementation of IFPLAN intervention components, one exploratory analysis will examine the primary outcome among women with disabilities according to self-reported intervention exposure. Exposure will be defined as reported exposure to at least one prespecified cluster-level IFPLAN component during the three-year intervention period: peer-to-peer sessions, Dillaliya household visits, community drama, Majalisa sessions, participatory scorecard activities, or accessibility changes at an IFPLAN-supported health facility. Radio, social-media exposure and the placebo IFPLAN Connect item will not contribute to this exposure definition.

The analysis will be restricted to participants meeting this exposure definition, and the comparison will remain between participants randomized to intervention and control clusters, using the same modelling approach as the primary analysis.

As intervention exposure is a post-randomization characteristic and was not randomized, this analysis will be considered exploratory and will not be interpreted as an estimate of the causal effect of intervention exposure.

Multiple Testing

No adjustment will be made for multiple testing.

Statistical Software

Analyses will be conducted using Stata version 18.0

References

1. Adewuya AO, Atilola O, Ola BA, Coker OA, Zachariah MP, Olugbile O, et al. Current prevalence, comorbidity and associated factors for symptoms of depression and generalised anxiety in the Lagos State Mental Health Survey (LSMHS), Nigeria. *Comprehensive Psychiatry*. 2018;81:60–5. DOI: <https://doi.org/10.1016/j.comppsy.2017.11.010>

Dummy Tables

Table 1 Demographic characteristics of participants by study arm and disability status

	Women with disabilities				Women without disabilities			
	Intervention		Control		Intervention		Control	
	n/N	%	n/N	%	n/N	%	n/N	%
Full endline sample (n=)								
(Time-invariant characteristics)								
...								
Baseline-endline sample (n=)								
(Time varying characteristics or those potentially affected by intervention)								
...								

Table 2: Participant reported exposure at endline to IFPLAN interventions in past A) 12 months and B) 3 years

Panel A: Exposure in the past 12 months

	Women with disabilities		Women without disabilities	
	Intervention n/N (%)	Control n/N (%)	Intervention n/N (%)	Control n/N (%)
Intervention activity				
Attended peer-to-peer sessions				
Household visited by Dillaliya				

**Attended community
drama**

**Husband attended
Majalisa session**

**Participatory
scorecard activity**

**Accessible facility
changes**

Social media

Radio

**Placebo (IFPLAN
Connect)**

Panel B: Exposure in the past 3 years

	Women with disabilities		Women without disabilities	
Intervention activity	Intervention n/N (%)	Control n/N (%)	Intervention n/N (%)	Control n/N (%)
Attended peer-to-peer sessions				
Household visited by Dillaliya				
Attended community drama				
Husband attended Majalisa session				
Participatory scorecard activity				
Accessible facility changes				
Social media				
Radio				

**Placebo (IFPLAN
Connect)**

Table 2: Analysis of outcomes

	With disabilities					Without disabilities					Interaction				
	Intervention		Control	aRR	95% CI	p-value	Intervention		Control	aRR	95% CI	p-value	Interaction effect*	95% CI	p-value
	n/N	%	n/N				n/N	%	n/N						
			%					%							
Access to family planning															
Knowledge ≥3 methods															
Demand for family planning															
Use of family planning (Modern method)															
Unmet need for family planning															
Intention to use family planning in the future															

*Exponentiated interaction coefficient which represents the ratio of adjusted treatment effects comparing individuals with disability to those without disability.

Table 4: Disability inclusion outcomes among women with disabilities

Outcome	Intervention Mean (SD)	Control Mean (SD)	Unadjusted mean difference (95% CI)	Adjusted mean difference (95% CI)	p-value*
Perceived inclusion/participation score (0–100)					
Perceived attitudes toward women with disabilities score (0–100)					

*p-value for the adjusted intervention effect.

Supplementary tables

- Supplementary Table S1:** Cluster-level characteristics at baseline

Characteristic	Intervention clusters (n = XX)	Control clusters (n = XX)	Total (n = XX)
Number of clusters			
Mean number of households screened			
Mean number of women with disabilities recruited per cluster			
Mean number of women without disabilities recruited per cluster			
Health facilities per cluster (mean)			
Health facility level (%)			
• Primary health facility			
• Secondary health facility			
Health facility type (%)			
• Public			
• Private			
Mean baseline modern contraceptive use (%)			

- Supplementary Table S2:** Impairments among women with disabilities by arm at baseline

	Women with Disabilities	
	Control	Intervention
N	n/N, %	n/N, %
Impairment Types		
Vision		
Hearing		
Mobility		
Communication		
Cognition		
Selfcare		
Anxiety		
Depression		

Number of Impairments		
1 impairment		
≥2 impairments		

• **Supplementary Table S3:** Cluster-level characteristics at baseline

Characteristic	Intervention clusters (n = XX)	Control clusters (n = XX)	Total (n = XX)
Number of clusters			
Mean number of households screened			
Mean number of women with disabilities recruited per cluster			
Mean number of women without disabilities recruited per cluster			
Health facilities per cluster (mean)			
Health facility level (%)			
• Primary health facility			
• Secondary health facility			
Health facility type (%)			
• Public			
• Private			
Mean baseline modern contraceptive use (%)			

• **Supplementary Table S4:** Impairments among women with disabilities by arm at baseline

	Women with Disabilities	
	Control	Intervention
N		
Impairment Types		
Vision		
Hearing		
Mobility		
Communication		
Cognition		
Selfcare		

Anxiety		
Depression		
Number of Impairments		
1 impairment		
≥2 impairments		

- **Supplementary Table S5: Sensitivity analyses for the primary outcome amongst women with disabilities only**

Analysis	Sample size (n)	Intervention (%)	Control (%)	Adjusted RR (95% CI)	p-value
Main analysis					
Excluding replacement participants recruited at endline (baseline-endline cohort)					
Excluding telephone respondents					

- **Supplementary Table S6: Exploratory analyses according to self-reported IFPLAN intervention exposure among women with disabilities**

Analysis	Sample size (n)	Intervention(%)	Control(%)	Adjusted RR (95% CI)	p-value
Main analysis					
Participants reporting ≥1 of any IFPLAN community-based or facility based exposures in past three years					

(excl the placebo mobile-phone intervention “IFPLAN Connect”)	
---	--

- **Supplementary Table S7:** Prespecified subgroup analysis of the primary outcome among women with disabilities

Subgroup	n	Intervention (%)	Control (%)	Adjusted RR (95% CI)	p-value
Main Analysis					
Women with ≥ 1 functional difficulty at recruitment other than anxiety/depression alone					