ISRCTN12671153 https://doi.org/10.1186/ISRCTN12671153

Investigating improvements in access to family planning for women with disabilities; a study of a disability-inclusive intervention in Kaduna city, Nigeria

Submission date
31/03/2023

Recruitment status
Recruiting

Registration date
17/04/2023

Overall study status
Ongoing

Last Edited
17/04/2025

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims

Women with disabilities are less likely to have access to family planning services compared to women without disabilities. Evidence on how to improve access for women with disabilities to these services is currently limited, particularly in low-resource settings. The Inclusive Family Planning (IFPLAN) project aims to increase access to contraceptives and reduce the need for family planning services amongst women with disabilities in Kaduna city, Nigeria. The intervention package will be designed and delivered by a consortium led by the international non-governmental organisation Sightsavers supported by BBC Media Action, in partnership with the Joint National Association of Persons with Disability (JONAPWD) and the Network of Disabled Women (NDW) in Nigeria. Interventions are intended to support demand-side, supply-side, and structural factors to support access to family planning. London School of Hygiene and Tropical Medicine (LSHTM) in partnership with Oxford Policy Management (OPM) Nigeria will conduct a study to understand if and how the interventions implemented at community and facility levels under the IFPLAN project have achieved their aims.

Who can participate?

Women 18 to 49 years with or without disabilities living in the study area of Kaduna city, Nigeria

What does the study involve?

Communities served by health facilities offering family planning services will be separated into 38 clusters and half will be randomly assigned to receive the IFPLAN community and facility level interventions and the other half will be randomly assigned to receive the standard provision of family planning services. Women aged 18 to 49 years with and without disabilities will be surveyed across all the clusters in each arm to understand their need for and access to family planning services before and after the implementation of the IFPLAN project.

What are the possible benefits and risks of participating?

Participants may feel uncomfortable discussing their experiences, as the survey asks about

sexual history and experience of intimate partner violence. Furthermore, answering the survey questions is likely to take a long time, so participants will be given soap/detergent as a small thank you. The information from the study will help to improve family planning services for women in this area. It may also help the government and organisations provide better family planning services.

Where is the study run from?
Intervention implementation is being led by Sightsavers under the IFPLAN project in Kaduna city, Nigeria. The study is led by the London School of Hygiene and Tropical Medicine in the UK, with data collection managed by Oxford Policy Management Nigeria.

When is the study starting and how long is it expected to run for?
April 2022 to July 2026

Who is funding the study?
Foreign, Commonwealth and Development Office (UK)

Who is the main contact?
Sarah Marks, sarah.marks@lshtm.ac.uk

Study website
https://www.lshtm.ac.uk/research/centres-projects-groups/penda#research

Contact information

Type(s)
Principal Investigator

Contact name
Prof Hannah Kuper

ORCID ID
http://orcid.org/0000-0002-8952-0023

Contact details
International Centre for Evidence in Disability
London School of Hygiene & Tropical Medicine
Keppel Street
London
United Kingdom
WC1E 7HT
+44 (0)20 7958 8333
Hannah.Kuper@lshtm.ac.uk

Type(s)
Scientific

Contact name
Ms Sarah Marks

ORCID ID

http://orcid.org/0000-0003-4804-3694

Contact details
International Centre for Evidence in Disability
London School of Hygiene & Tropical Medicine
Keppel Street
London
United Kingdom
WC1E 7HT
-
Sarah.Marks@lshtm.ac.uk

Type(s)
Public

Contact name
Ms Sarah Marks

Contact details
International Centre for Evidence in Disability
London School of Hygiene & Tropical Medicine
Keppel Street
London
United Kingdom
WC1E 7HT
-
Sarah.Marks@lshtm.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
3

Study information

Scientific Title
Improving access to family planning for women with disabilities in Kaduna city, Nigeria: a cluster-randomized controlled trial with integrated process evaluation

Acronym
IFPLAN Evaluation

Study objectives
Inclusive Family Planning (IFPLAN) interventions will increase access to family-planning methods for women of reproductive age with disabilities in Kaduna city, Nigeria.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 26/08/2022, National Health Research Ethics Committee (Federal Ministry of Health, Federal Secretariat Complex Shehu Shagari Way, Garki, Abuja P.M.B. 083, Garki-Abuja, Nigeria; +234 (0)9 523 8367; info@nhrec.net), ref: NHREC/01/01/2007-26/08/2022
2. Approved 15/11/2022 (for baseline survey), London School of Hygiene and Tropical Medicine Observational / Interventions Research Ethics Committee (Keppel St, London, WC1E 7HT, UK; +44 (0)20 7636 8636; ethics@lshtm.ac.uk), ref: 27577

Study design
Unmasked cluster randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Community

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Access to family planning amongst women of reproductive age with disabilities

Interventions
A cluster-randomized controlled trial will be used to evaluate interventions delivered under the IFPLAN project at health facility and community levels in comparison to ‘standard’ state provision of family planning services, in the context of state-wide and national broadcast media and advocacy for both arms. Clusters in the intervention arm will receive interventions that aim to address supply-side and demand-side barriers to accessing family planning among women with disabilities. Demand-side activities evaluated by the trial will include interpersonal communication activities, such as: a) selection, training and delivery of structured group sessions by inclusive champions; b) the use of audio devices for group listening to radio stories and discussion sessions; c) the use of a board game to engage young people in the messages, myths and benefits of family planning; d) printed materials to aid discussions; e) community drama; f) household visits for people with disabilities in the home where needed; and g) town hall meetings. Intervention activities to support the supply side will focus on providing more inclusive service provision for people with disabilities, and activities will include accessibility

audits, disability-inclusive training, and participatory scorecard assessments of family planning services. Intervention implementation will also be supported by an adaptive management approach, using data to target and adjust programme components.

Randomization will be conducted based on the health facility catchment area, with a total of 38 clusters. Cluster assignment to the intervention and control arms will be conducted at one timepoint before the start of the trial during a multi-stakeholder event organised by Sightsavers. Cluster allocation will be conducted through a random draw conducted by government officials in Kaduna during the event. Blocked randomization will be used, with an allocation ratio of one to one for intervention and control arms, with a block size of 19 clusters. The first block will be allocated to the intervention arm and the second block to the control arm.

It was calculated that at least 950 women aged 18 to 49 years with disabilities (475 in each arm) will be recruited to detect a 50% increase in access compared to the control arm. For each woman with disabilities enrolled a neighbouring woman without disabilities in the same cluster and age group will be recruited to assess whether the intervention has a specific effect amongst women with disabilities.

Outcomes will be measured through a baseline survey prior to implementation and a post-intervention endline survey conducted after 1 year of project implementation, complemented by an integrated process evaluation.

Total duration of intervention: 12 months; Follow-up: 18 months after baseline.

Updated 17/04/2025:
Outcomes will be measured through a baseline survey prior to implementation and a post-intervention endline survey conducted after approximately 2 years of project implementation, complemented by an integrated process evaluation.

Total duration of intervention: approx. 24 months; Follow-up: 30 months after baseline.

Intervention Type
Mixed

Primary outcome measure
Access to family planning measured at endline based on a composite of beliefs about using services if needed, including: knowledge of at least three modern contraceptive methods available; where to access modern family planning; provider location and list of available family planning services; and belief that they could use services if they needed them.

Secondary outcome measures
1. Knowledge of family planning
2. Demand for family planning
3. Use of family planning (modern method)
4. Unmet need for family planning
5. Perceived attitudes towards women with disabilities
All measured via a survey at endline

Overall study start date
04/04/2022

Completion date
31/07/2026

Eligibility

Key inclusion criteria
The participants in the trial will be women with disabilities, matched with women without disabilities from the same cluster. These women will be evenly distributed across control and intervention arms. Participant eligibility will be determined based on the following inclusion criteria:
1. People who identify as women, aged 18-49 years (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 the enhanced question on self-care, or ‘daily’ and ‘a lot’ to the 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

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Upper age limit
49 Years

Sex
Female

Target number of participants
950 women with disabilities and 950 women without disabilities across 38 clusters

Key exclusion criteria
Participants will be excluded if they are not able to consent on their own – with the exception of the process evaluation, where those with intellectual difficulties may be interviewed (with their caregiver’s consent) in order to ensure feedback from people with a range of impairment types.

Date of first enrolment
09/12/2022

Date of final enrolment
31/01/2026

Locations

Countries of recruitment

Nigeria

Study participating centre
Oxford Policy Management (OPM) Nigeria
House 2, No.16 Mafemi Crescent
Utako
Abuja
Nigeria
-

Sponsor information

Organisation
London School of Hygiene & Tropical Medicine

Sponsor details
Keppel St
London
England
United Kingdom
WC1E 7HT
+44 (0)20 7636 8636
ethics@lshtm.ac.uk

Sponsor type
University/education

Website
http://www.lshtm.ac.uk/

ROR
https://ror.org/00a0jsq62

Funder(s)

Funder type
Government

Funder Name
Foreign, Commonwealth and Development Office

Alternative Name(s)

Foreign, Commonwealth & Development Office, Foreign, Commonwealth & Development Office, UK Government, FCDO

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publications in peer-reviewed journals. Findings from the research will also be disseminated through conferences, and local advocacy workshops to share results and learning from the study.

Intention to publish date
31/07/2025

Individual participant data (IPD) sharing plan
The datasets generated during the current study will be stored in a publicly available repository, specifically LSHTM's Data Compass (https://datacompass.lshtm.ac.uk/), alongside project documentation and a data-user guide. The data will be made available 12 months after the completion of endline data collection. Data will be made available through open access. Explicit consent from participants has been requested to make the data open access. No identifiers will be included in the data.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		05/01/2024	08/01/2024	Yes	No