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ENSURING TRANSPARENCY AND ACCOUNTABILITY: PACTR'S IMPACT ON CLINICAL TRIAL REGISTRATION IN AFRICA

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The South African Medical Research Council
recognizes the catastrophic and persisting consequences of colonialism and apartheid, including land dispossession and the intentional imposition of educational and health inequities.

Acknowledging the SAMRC's historical role and silence during apartheid, we commit our capacities and resources to the continued promotion of justice and dignity in health research in South Africa.

Plan

- Who are we?

- What is a clinical trial registry?

- A delve into PACTR

SAMRC: Mandate and mission

- The SAMRC was established in 1969 and mandated by an Act of the Parliament of South Africa to improve the health & quality of life of South Africans.

- The SAMRC is managed & controlled by a Board

- The mission of the SAMRC is to advance health and quality of life and address inequality by conducting and funding relevant and responsive health research, capacity development, innovation, and research translation

The SAMRC in brief

SAMRC research priorities : research programmes

Health Promotion and Disease Prevention
10 units

Maternal, Child and Women's Health
4 units

HIV, AIDS, TB and Other Communicable Diseases
4 units

Health Systems Strengthening
6 units

Public Health Innovation
4 units

Biomedical Research
9 units

Clinical Trial Registry

A clinical trial registry is a database in which key administrative and scientific information about planned, ongoing and completed trial, sufficient to identify that trials existence, is stored.

Cochrane South Africa hosts two clinical trial databases

Pan African Clinical Trial Registry (PACTR)

A primary registry of the WHO-ICTRP (World Health Organisation's International Clinical Trial Registry Platform)

South African Clinical Trial Register (SANCTR)

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Search trial

Register a trial

Map of African trials

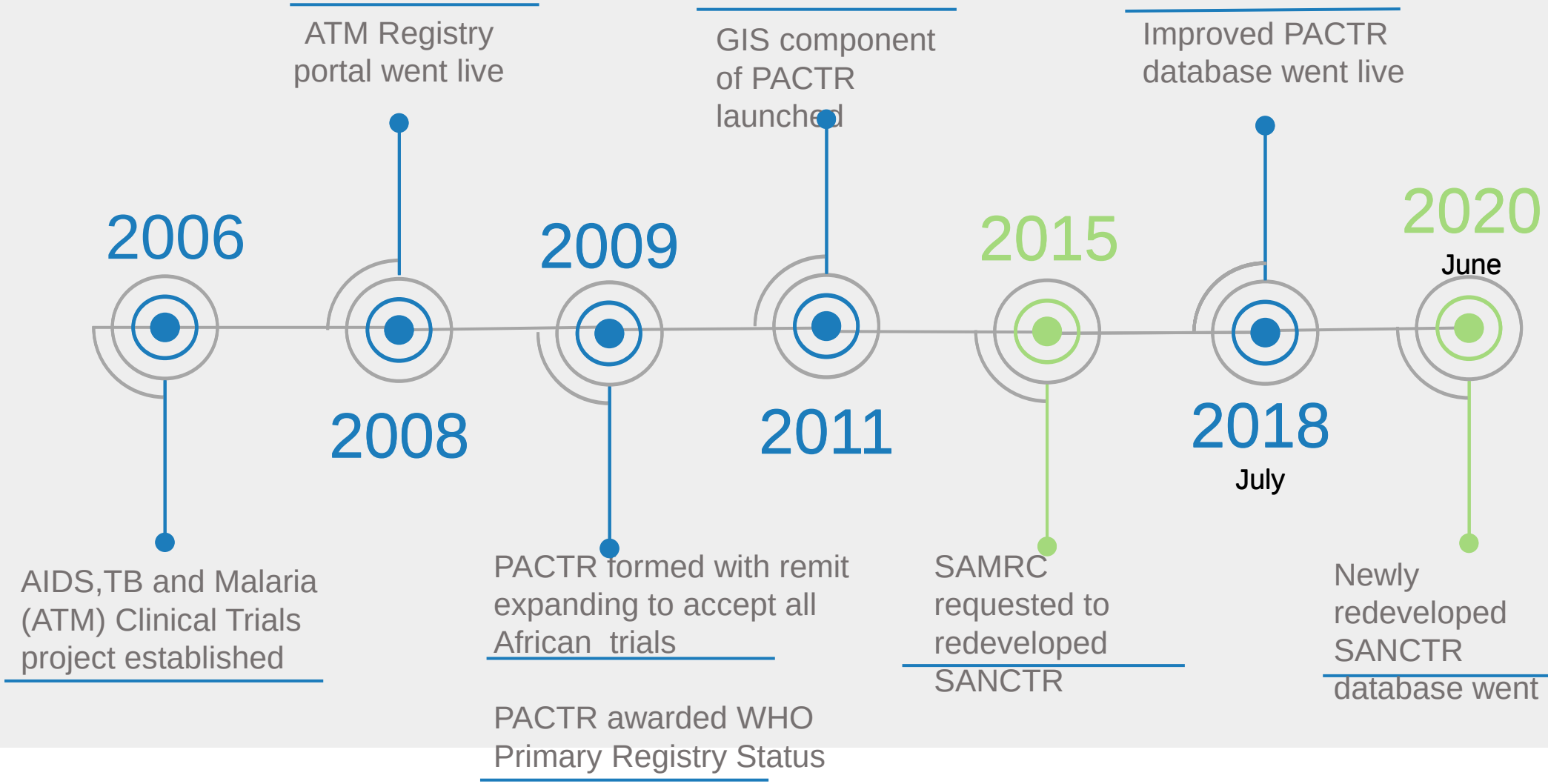
Welcome to PACTR

The Pan African Clinical Trials Registry (PACTR) is a regional register of clinical trials conducted in Africa. The registry is an African initiative serving the needs of Africans. It provides an open-access platform where clinical trials can be registered free of charge. The PACTR aims to increase clinical trial registration in Africa by developing awareness of the need to register trials and supporting trialists during registration.

In addition, PACTR provides a searchable, electronic database of planned trials and trials currently in progress. Those wishing to search the database of trials, can do so from the homepage, by clicking on the "search" link. There is no need to register on the site if you simply want to search the database.

The PACTR is unique in recognising that African trialists face additional challenges in trial registration and seeks to provide feasible ways of overcoming these. For example, a common problem for individuals living in sub-Saharan Africa is limited, unreliable and costly internet access. With this

Overview of PACTR



Why register a clinical trial?

- ✓ Historical lack of transparency in human research
  - Unpublished trials
  - Biased reporting
- ✓ Promotes efficient allocation of resources
- ✓ Avoids unnecessary duplication of studies
- ✓ Increases trust in clinical research by the public

Importance of Transparency and Accountability in Clinical Trials

Ensures ethical conduct: Transparency fosters adherence to ethical principles and guidelines in research.

Builds trust: Transparent practices instill confidence in participants, healthcare professionals, and the public.

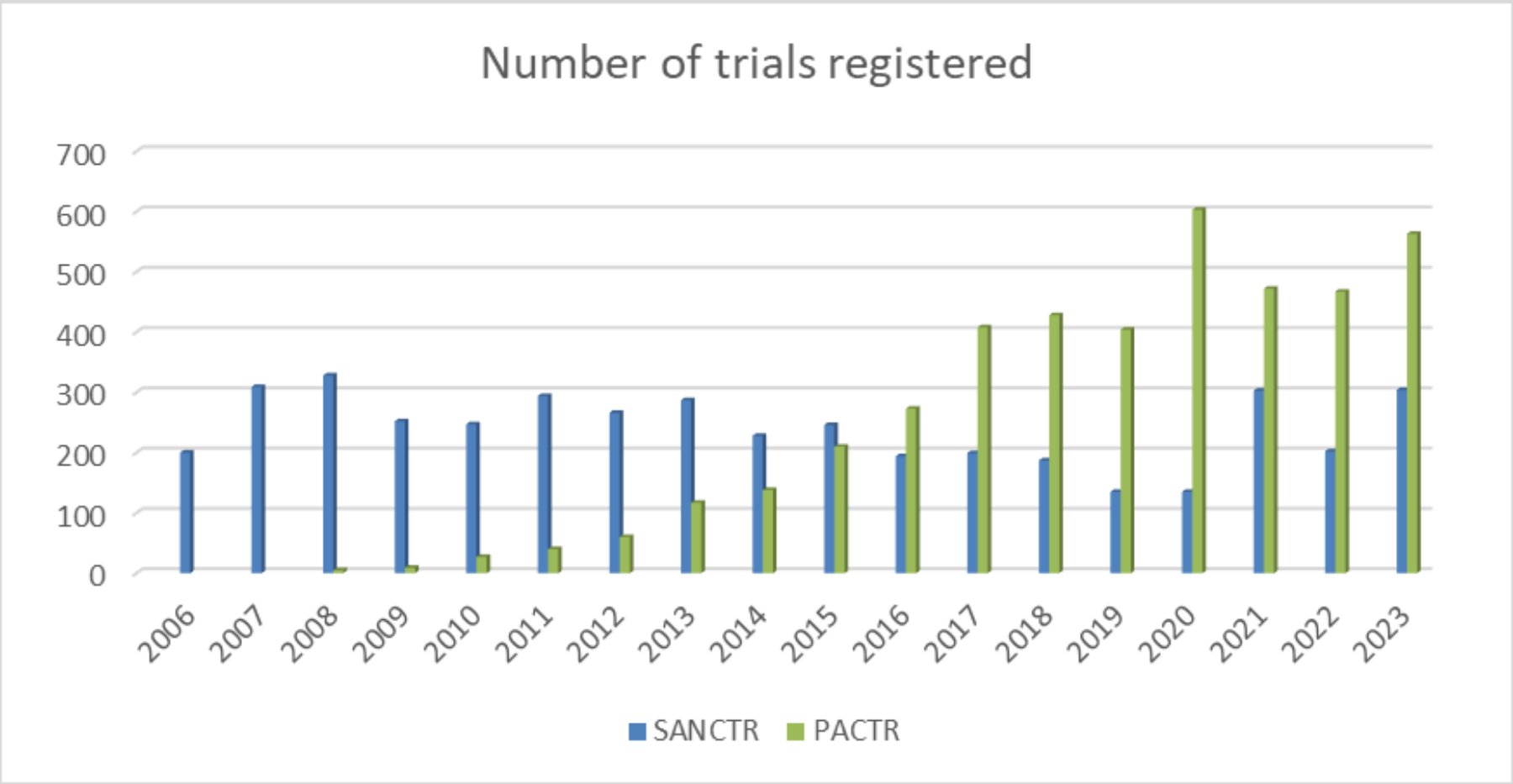
Facilitates peer review: Openness allows for scrutiny and validation of research methods and findings by peers.

Advances scientific knowledge: Transparent reporting promotes the accumulation of reliable data for further research and innovation.

Protects participant rights: Accountability safeguards the welfare and rights of research participants.

Enhances public health: Transparent reporting of trial results enables informed decision-making in healthcare and policy.

The growth in PACTR registration



Data: December 2023

PACTR's Role in Enhancing Clinical Trial Registration in Africa

Centralisation: Provides a centralized platform for registering clinical trials conducted across Africa.

Standardisation: Ensures adherence to international standards and guidelines for trial registration and reporting.

Accessibility: Facilitates easy access to trial information for researchers, healthcare professionals, and the public.

Capacity Building: Offers training and support to researchers and institutions to improve understanding and compliance with registration requirements.

Visibility: Increases the visibility of African research on a global scale, attracting collaboration and investment.

Quality Assurance: Implements measures to verify and validate trial information, enhancing the reliability of registered data.

Advocacy: Advocates for policies and initiatives that promote transparency and accountability in clinical research practices.

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Impact Assessment of PACTR on Clinical Trial Transparency (1)

- **Increased Registration**
  - ✓ Demonstrated significant increase in the number of registered clinical trials in Africa since PACTR's establishment.

- **Transparency**
  - ✓ Facilitated transparent reporting of trial protocols, results, and outcomes, contributing to research integrity.

- **Accountability**
  - ✓ Holding researchers and sponsors accountable for adhering to registration and reporting requirements.

Impact Assessment of PACTR on Clinical Trial Transparency (2)

Improved Research Practices

Encouraged adoption of best practices in research conduct and reporting.

Empowered Stakeholders

Empowered stakeholders including researchers, regulators, and funders with reliable trial information for decision-making.

Contributed to Public Health

Enhanced evidence-based decision-making in healthcare and policy, ultimately benefiting public health outcomes.

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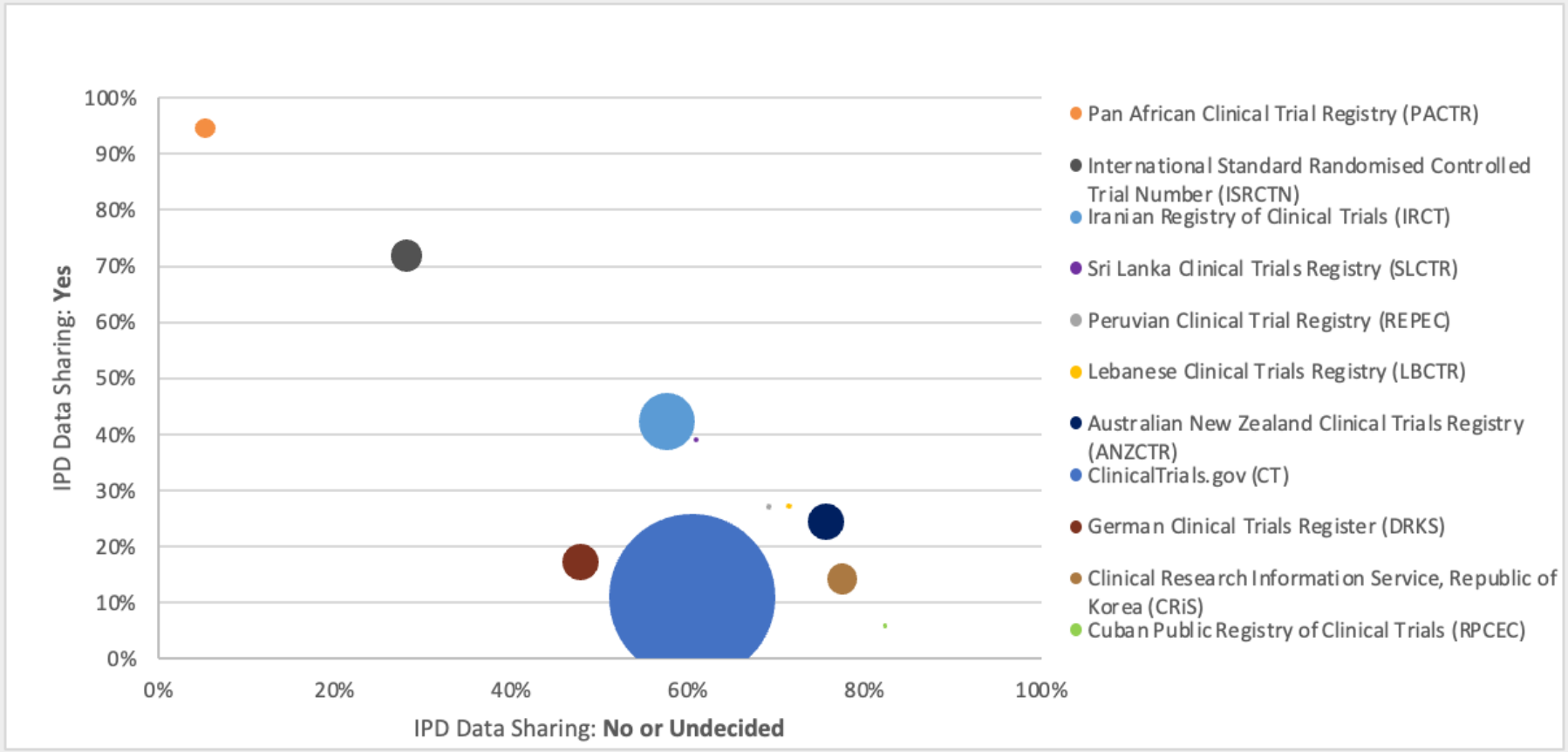
PACTR's Influence on Research Practices (1)



- Information on IPD sharing ranges across the 18 registries
- Cuban Public Registry of Clinical Trials (5.9%) compared to Pan African Clinical Trial Registry (94.6%)
- Other registries (n= 7) had little or no available information in study registrations for 2019 and 2020

Merson L, **Ndwandwe D**, Malinga T, Paparella G, Oneil K, Karam G, Terry RF. Promotion of data sharing needs more than an emergency: An analysis of trends across clinical trials registered on the International Clinical Trials Registry Platform. Wellcome Open Res. 2022 Mar 21;7:101. doi: 10.12688/wellcomeopenres.17700.1. PMID: 35419494; PMCID: PMC8980676.

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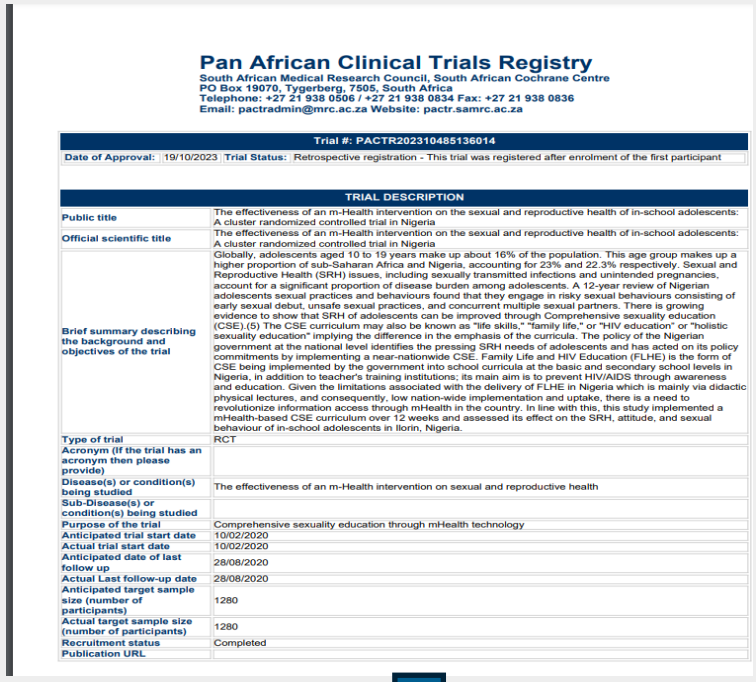
PACTR's Influence on Research Practices (2)



Pan African Clinical Trials Registry

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PO Box 19070, Tygerberg, 7505, South Africa
Telephone: +27 21 938 0506 / +27 21 938 0834 Fax: +27 21 938 0836
Email: pactradmin@mrc.ac.za Website: pactr.samrc.ac.za

Trial #: PACTR202310485136014

Date of Approval:	19/10/2023	Trial Status:	Retrospective registration - This trial was registered after enrolment of the first participant

TRIAL DESCRIPTION

Public title	The effectiveness of an m-Health intervention on the sexual and reproductive health of in-school adolescents: A cluster randomized controlled trial in Nigeria
Official scientific title	The effectiveness of an m-Health intervention on the sexual and reproductive health of in-school adolescents: A cluster randomized controlled trial in Nigeria
Brief summary describing the background and objectives of the trial	Globally, adolescents aged 10 to 19 years make up about 16% of the population. This age group makes up a higher proportion of sub-Saharan Africa and Nigeria, accounting for 23% and 22.3% respectively. Sexual and Reproductive Health (SRH) issues, including sexually transmitted infections and unintended pregnancies, account for a significant proportion of disease burden among adolescents. A 12-year review of Nigerian adolescents sexual practices and behaviours found that they engage in risky sexual behaviours consisting of early sexual debut, unsafe sexual practices, and concurrent multiple sexual partners. There is growing evidence to show that SRH of adolescents can be improved through Comprehensive sexuality education (CSE).(5) The CSE curriculum may also be known as "life skills," "family life," or "HIV education" or "holistic sexuality education" implying the difference in the emphasis of the curricula. The policy of the Nigerian government at the national level identifies the pressing SRH needs of adolescents and has acted on its policy commitments by implementing a near-nationwide CSE. Family Life and HIV Education (FLHE) is the form of CSE being implemented by the government into school curricula at the basic and secondary school levels in Nigeria, in addition to teacher's training institutions; its main aim is to prevent HIV/AIDS through awareness and education. Given the limitations associated with the delivery of FLHE in Nigeria which is mainly via didactic physical lectures, and consequently, low nation-wide implementation and uptake, there is a need to revolutionize information access through mHealth in the country. In line with this, this study implemented a mHealth-based CSE curriculum over 12 weeks and assessed its effect on the SRH, attitude, and sexual behaviour of in-school adolescents in Ilorin, Nigeria.
Type of trial	RCT
Acronym (If the trial has an acronym then please provide)	
Disease(s) or condition(s) being studied	The effectiveness of an m-Health intervention on sexual and reproductive health
Sub-Disease(s) or condition(s) being studied	
Purpose of the trial	Comprehensive sexuality education through mHealth technology
Anticipated trial start date	10/02/2020
Actual trial start date	10/02/2020
Anticipated date of last follow up	28/08/2020
Actual Last follow-up date	28/08/2020
Anticipated target sample size (number of participants)	1280
Actual target sample size (number of participants)	1280
Recruitment status	Completed
Publication URL	

OUTCOMES

Type of outcome	Outcome	Timepoint(s) at which outcome measured
Primary Outcome	Primary outcome was participants mean scores in SRH knowledge, SRH attitude and RSB of participants	Measured at baseline, immediately after the intervention and 3 months after the intervention
Secondary Outcome	Factors influencing the primary outcomes (SRH knowledge, attitude and sexual behaviour) using multivariate analysis using binary logistic regression.	Immediately after the intervention

Akande *et al. Reproductive Health* (2024) 21:6
https://doi.org/10.1186/s12978-023-01735-4

Reproductive Health

RESEARCH Open Access

The effectiveness of an m-Health intervention on the sexual and reproductive health of in-school adolescents: a cluster randomized controlled trial in Nigeria

Oluwatosin Wuraola Akande[1*], Moise Muzigaba[2], Ehimario Uche Igumbor[3,4], Kelly Elimian[5,6], Oladimeji Akeem Bolarinwa[1], Omotosho Ibraheem Musa[1] and Tanimola Makanjuola Akande[1]

Abstract

Background The implementation of the country-wide comprehensive sexuality education (CSE) curriculum among in-school adolescents remains abysmally low and mHealth-based interventions are promising. We assessed the effect of a mHealth-based CSE on the sexual and reproductive health (SRH) knowledge, attitude and behaviour of in-school adolescents in Ilorin, northcentral Nigeria.

Outcome measures

The primary outcome was participants mean scores in SRH knowledge, SRH attitude and RSB of participants, measured at baseline, T_1 and T_2.

Akande OW, Muzigaba M, Igumbor EU, Elimian K, Bolarinwa OA, Musa OI, Akande TM. The effectiveness of an m-Health intervention on the sexual and reproductive health of in-school adolescents: a cluster randomized controlled trial in Nigeria. Reprod Health. 2024 Jan 13;21(1):6. doi: 10.1186/s12978-023-01735-4. PMID: 38218840; PMCID: PMC10788027.

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Challenges for PACTR and Clinical Trial Registration in Africa

- Low awareness and adoption of PACTR among researchers and institutions hinder its full potential
- Insufficient resources and training opportunities for researchers to comply with registration requirements
- Ensuring the accuracy and completeness of registered trial information to maintain credibility
- Addressing disparities in regulatory frameworks across African countries to streamline registration processes
- Securing long-term funding and support for PACTR's operations and development.

Future Directions for PACTR and Clinical Trial Registration in Africa

Enhanced Outreach: increase awareness and promote the benefits of PACTR through targeted outreach and educational initiatives.

Capacity Development: provide training and resources to build capacity among researchers and institutions for effective trial registration.

Technology Upgrades: invest in technology to improve the user experience, data management, and reporting capabilities of PACTR.

Collaborative Partnerships: Strengthen Collaboration With regulatory agencies, research institutions, and international organizations to harmonize standards and enhance compliance.

Continuous Improvement: Regularly Assess And Refine PACTR's Processes and Functionalities to Meet evolving needs and international best practices in clinical trial registration.

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