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How access to higher-quality care services affect the use of medical care for young children in urban South Africa

Submission date	**Recruitment status**	[_] Prospectively registered
24/02/2025	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/02/2025	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
25/02/2025	Other	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
In many low-income areas, public healthcare services often suffer from poor quality and low accountability, leading people to delay using these services even when they are free. In South Africa, most people rely on free government healthcare, which is often of low quality and involves long waiting times. The South African government is considering a national health insurance scheme to provide free access to higher-quality private healthcare. This study aims to find out if access to free private care reduces under-use of services for children, if it increases overuse, and if the distance to private providers affects these outcomes.

Who can participate?
The study will include about 1,500 primary caregivers of at least one child aged six or under who do not have medical insurance.

What does the study involve?
Participants will be randomly assigned to one of three groups: a control group with free access to government facilities, or one of two treatment groups with free access to private providers located either relatively close or far away. Participants will complete two surveys at the start and end of the 12-week study period, keep a daily diary of their child's symptoms and healthcare use, and have weekly 10-minute visits from a researcher to collect data from the diary.

What are the possible benefits and risks of participating?
There are no direct risks for participants. Those in the treatment groups will get subsidised access to private care for one of their children. All participants will continue to have access to free public healthcare services. Participants' confidentiality will be protected, and results will be reported only at the group level.

Where is the study run from?
Centre for Health Policy (CHP) at the University of the Witwatersrand (South Africa)

When is the study starting and how long is it expected to run for?
March 2022 to August 2024

Who is funding the study?
Medical Research Council, UKRI Reference MR/T023635/1 (UK)

Who is the main contact?
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Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
NCT06275867

Secondary identifying numbers
SOPRIMA//T023635

Study information

Scientific Title
The impact of access to higher-quality care services on healthcare utilization for children aged under 5 years: a randomized controlled trial in urban South Africa

Acronym
SOPRIMA

Study objectives
1. Free private care reduces underuse of services for children
2. Free private care increases overuse of services for children
3. These effects are mitigated by the distance between households and private providers

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 18/03/2022, University of the Witswatersrand, Human Research Ethics Committee (non-medical) (1 Jan Smuts Avenue, Braamfontein, Johannesburg, 2000, South Africa; +27(0) 11 717 1408; hrecnon-medical@wits.ac.za), ref: H22/03/32

2. Approved 17/03/2024, London School of Economics Research Ethics Committee (Houghton Street, London, WC2A 2AE, United Kingdom; +44 (0)20 7852 3629; research.ethics@lse.ac.uk), ref: 57203

Study design
Multicentre interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice, Home

Study type(s)
Other

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
Common conditions in children under-5

Interventions
Participants are the primary caregivers of at least one child aged five years or under. Participants are randomly allocated to one of three groups in equal proportions: a control group (CONTROL) with default free access to government facilities; a treatment group with free access to government facilities and to a network of private providers located close by (CONVENIENT); or a treatment group with free access to government facilities and to a network of private providers located far away (INCONVENIENT). In treatment groups, participants have unlimited access for one of their children (chosen at random) to private providers for 12 weeks. Randomisation is done after recruitment using a computer.

Intervention Type
Other

Primary outcome measure
1. Underuse: the proportion of caregivers who do not seek 'recommended' care for their child at least once , measured over 12 weeks with health diaries (recommended care is defined against community-IMCI guidelines).
2. Overuse : the proportion of caregivers who seek unnecessary care for their child at least once , measured over 12 weeks with health diaries (unnecessary care is defined against community-IMCI guidelines: care is unnecessary if it does not meet the threshold of recommended care).

Secondary outcome measures
1. Appropriate, timely use: the proportion of caregivers who seek care for their child exactly when 'recommended' at least once, measured over 12 weeks with health diaries (recommended care is defined against community-IMCI guidelines).
2. Number of appropriate, timely visits: the number of timely visits made by a caregiver for their child, measured over 12 weeks with health diaries (a timely visit is done exactly when care is 'recommended' accoridng to the community-IMCI guidelines).
3. Appropriate, delayed use: the proportion of caregivers who seek care for their child after it is 'recommended' at least once, measured over 12 weeks with health diaries (recommended care is defined against community-IMCI guidelines).
4. Number of appropriate, delayed visits: the number of delayed visits made by a caregiver for their child, measured over 12 weeks with health diaries (a delayed visit is done after care is 'recommended' accoridng to the community-IMCI guidelines).
5. Underuse of care: the number of days of illness where care-seeking is recommended but not sought by the child's parent or guardian measured through daily symptoms and health-seeking data collected over 12 weeks.
6. Overuse : the proportion of primary health care visits made by the household that are considered unnecessary measured through daily symptoms and health-seeking data collected over 12 weeks (unnecessary care is defined against community-IMCI guidelines: care is unnecessary if it does not meet the threshold of recommended care).
7. Public care use: the proportion of caregivers who seek care for their child at least once at a government health care facility, measured over 12 weeks with health diaries.
8. Private care use: the proportion of caregivers who seek care for their child at least once at a private GP, measured over 12 weeks with health diaries.

9. Pharmacy use: the proportion of caregivers who seek care for their child at least once in a pharmacy, measured over 12 weeks with health diaries.
10. Out-of-pocket expenditures: the total direct (consultations, drugs) and indirect (transport) expenditures spent on health care, measured over 12 weeks with health diaries.
11. Waiting time: time spent by caregivers on transport and at facilities waiting to seek care, measured over 12 weeks with health diaries.
12. Health knowledge: Index of knowledge of parents in relation to preventive and curative care. Parents will answer as series of knowledge questions relative to care-seeking patterns for children (with correct and incorrect responses). For each individual, a score will be computed by adding up all of the correct responses (1 point per correct response, 0 for incorrect), so a higher score will reflect a better knowledge. Captured in the endline survey at 12 weeks after the start of the intervention.

Overall study start date
18/03/2022

Completion date
30/08/2024

Eligibility

Key inclusion criteria
1. The parent or primary caregiver who has a child aged under 5 years old and over 2 months old
2. Resident in selected clusters of the Soweto Health and Demographic Surveillance site (HDSS) that are part of the Child Health and Mortality Prevention Surveillance (CHAMPS) study.

Participant type(s)
Other

Age group
Adult

Lower age limit
16 Years

Upper age limit
90 Years

Sex
Both

Target number of participants
1500

Total final enrolment
1415

Key exclusion criteria
1. Is planning to move out of the area in the next 3 months
2. Has private medical aid

Date of first enrolment
19/01/2024

Date of final enrolment
16/02/2024

Locations

Countries of recruitment
South Africa

Study participating centre
Mapetla HDSS Soweto Cluster
Mapetla, Soweto
Johannesburg
South Africa
1818

Study participating centre
Meadowlands East Zone 4 HDSS Soweto Cluster
Meadowlands East Zone 4, Soweto
Johannesburg
South Africa
1852

Study participating centre
Meadowlands East Zone 5 HDSS Soweto Cluster
Meadowlands East Zone 5, Soweto
Johannesburg
South Africa
1852

Study participating centre
Mofolo North HDSS Soweto Cluster
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Study participating centre

Phiri HDSS Soweto Cluster
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ROR
https://ror.org/03rp50x72

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
31/12/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be published as a supplement to the results publication

IPD sharing plan summary
Published as a supplement to the results publication