

A multi-site intervention study comparing health outcomes of MAMA South Africa users versus standard of care

Submission date 13/02/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 20/02/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 23/10/2020	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

This research was done to try to measure the impact of a project which sent pregnancy and child support information to pregnant women and new mothers in Johannesburg, South Africa. The information was sent by text message twice a week starting during pregnancy and continued until the child was one year of age.

Who can participate?

Women over the age of 18 who received ANC and PNC services at one of the participating ANC /PNC sites during the study period, and who delivered with a skilled birth attendant at one of two participating delivery sites

What does the study involve?

The study involves receiving informative text messages on a mobile phone twice a week from the week participants sign up during pregnancy and until their newborn child is 12 months old. Some participants are invited to attend an interview about the text messages.

What are the possible benefits and risks of participating?

The direct benefit of the study is receiving the information in the text messages. These are not expected to pose any risk to the participants.

Where is the study run from?

1. Wits Reproductive Health and HIV Institute (South Africa)
2. Karolinska Institutet (Sweden)

When is the study starting and how long is it expected to run for?

July 2012 to May 2015

Who is funding the study?

1. United Nations Foundation
2. Babycentre

3. Johnson and Johnson
4. mHealth Alliance

Who is the main contact?

Dr Jesse Coleman
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Contact information

Type(s)

Scientific

Contact name

Dr Jesse Coleman

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Contact details

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

MAMA

Study information

Scientific Title

Evaluating the effectiveness of the MAMA South Africa mHealth intervention from health care utilisation, cost-effectiveness and user perspectives

Acronym

MAMA SA

Study objectives

The MAMA South Africa intervention is a cost-effective way of improving attendance to antenatal and postnatal care.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Human Research Ethics Committee (Medical) at the University of the Witwatersrand in Johannesburg, Research Office, Faculty of Health Sciences, Phillip Tobias Building, Offices 301-304, 3rd Floor, Cnr York Road and 29 Princess of Wales Terrace, Parktown, Johannesburg, 2193, South Africa. Research Administrator: Mr Rhulani (Mkansi Rhulani.Mkansi@wits.ac.za) or Ms Zanele Ndlovu (zanele.ndlovu@wits.ac.za), Tel: +27 (0)11 717 1252/2700/1234/2656, 31/01/2014

Study design

Multi-centre intervention study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Other

Study type(s)

Prevention

Participant information sheet

Health condition(s) or problem(s) studied

Maternal health, newborn health, HIV

Interventions

The mHealth intervention consisted of twice-weekly informative and stage-based maternal health information text messages sent to women during pregnancy until their child was one year of age. The intervention was offered to all pregnant women receiving ANC care at the intervention sites and supplemented the clinical standard of care offered. Intervention participants could join the SMS intervention between their 5th and 39th week of pregnancy. An additional 104 messages were sent postnatally, and included reminders for each vaccination during the first year. The intervention ran from July 2012 to August 2014. The last enrolled patient was followed until May 2015.

Intervention Type

Behavioural

Primary outcome measure

Attendance to antenatal care, collected from clinical ANC records (number of visits during the pregnancy)

Secondary outcome measures

1. Childhood immunizations received, collected from the "road to Health" booklets that each infant receives and where immunization data are recorded, at birth, age 6 weeks, age 10 weeks, age 14 weeks, and age 9 months
2. Postnatal infant HIV testing collected from the delivery site PCR testing database at age 6 weeks
3. Birth outcomes collected from the maternal register database at the delivery site at birth
4. Cost-effectiveness calculated based on MAMA user costs, health care system costs and programmatic costs which were entered in the Lives Saved Tool (LiST), a tool used to model the impact of scaling-up health-related interventions used to reduce maternal, neonatal and child mortality costs collected retrospectively including data from planning of intervention

Overall study start date

02/07/2012

Completion date

31/05/2015

Eligibility

Key inclusion criteria

1. Over the age of 18 at recruitment
2. Received ANC and PNC services at one the participating ANC/PNC sites during the study period
3. Delivered with a skilled birth attendant at one of two participating delivery sites
4. Have had regular access to a cellular phone

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

504 in control and 504 in intervention group

Total final enrolment

821

Key exclusion criteria

1. Younger than 18 years of age
2. Did not give consent to participate
3. Did not fulfil inclusion criteria

Date of first enrolment

02/07/2012

Date of final enrolment

21/08/2014

Locations

Countries of recruitment

South Africa

Sweden

Study participating centre**Wits Reproductive Health and HIV Institute**

Wits RHI HQ, Hillbrow Health Precinct, 22 Esselen Street, Hillbrow
Johannesburg
South Africa
2001

Study participating centre**Karolinska Institutet**

Department of Public Health, Tomtebodavägen 18A
Stockholm
Sweden
17176

Sponsor information

Organisation

Wits Reproductive Health and HIV Institute

Sponsor details

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Hillbrow Health Precinct
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Johannesburg
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Sponsor type
University/education

Website
<http://www.wrhi.ac.za/>

Funder(s)

Funder type
Industry

Funder Name
United Nations Foundation

Funder Name
Babycentre

Funder Name
Johnson and Johnson

Alternative Name(s)
Johnson & Johnson, johnson & Johnson Services, Inc., Johnson&Johnson, , Johnson & Johnson Private Limited, , J&J, JNJ

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Funder Name
mHealth Alliance

Results and Publications

Publication and dissemination plan

This study has resulted in five sub-studies, three about uptake of ANC and PNC services, one on cost-effectiveness and one qualitative study on user perceptions. Two papers have already been published (July 2017 and July 2018 - see publication list). One paper is being submitted for consideration in March 2019, another will be submitted before June 2019.

Intention to publish date

01/03/2019

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Jesse Coleman (denots@gmail.com).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	20/10/2020	23/10/2020	Yes	No