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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

Registration date
20/02/2019

Overall study status
Completed

Last Edited
23/10/2020

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
denots@gmail.com

Contact information

Type(s)
Scientific

Contact name
Dr Jesse Coleman

ORCID ID
https://orcid.org/0000-0002-3601-7854

Contact details
Wits RHI HQ
Hillbrow Health Precinct
22 Esselen Street
Hillbrow
Johannesburg
South Africa
2001
+17783022837
denots@gmail.com

Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Multi-centre intervention study

Study type(s)
Prevention

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

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Female

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

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

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