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Research for maternal and child remote health checkups using telemedicine in Bangladesh

Submission date
15/07/2021

Recruitment status
No longer recruiting

Registration date
19/07/2021

Overall study status
Ongoing

Last Edited
16/12/2022

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Maternal and child health has greatly improved owing to the United Nation's Millennium Development Goals. However, the worldwide incidence of preventable deaths is still high. Bangladesh is not an exception. The country's MDG targets (143 maternal death per 100,000 and 48 under-five death per 1000) were not attained. This may be attributed to the lower coverage of maternal and child health care.

The portable health clinic is an eHealth system that comprises a set of sensor devices in an attache case, a data transmission system linked to a mobile network, and a data management application. The device was developed in collaboration between Grameen Communications (GC) and Kyushu University (KU). The portable health clinic has been used for eHealth checkups of over 40,000 to prevent non-communicable diseases such as diabetes and hypertension in Bangladesh. It is particularly useful for people who live in remote areas where access to health care is limited and could be used for other health check-ups such as for maternal and child health.

The aims of this study are:
1. To examine the effectiveness in health care access among pregnant women and infants using the portable health clinic
2. To examine the effectiveness in health status among adolescent and pregnant women introducing the portable health clinic.

Who can participate?
Pregnant women 15 - 49 years old and their infants who live in Chhaygaon union (Bangladesh)

What does the study involve?
Local health workers collect women and infants' health status data using medical devices. When data are entered into the data management application, they are at once categorized into four stages: healthy, caution, affected, and emergent, following the triage logic. The health workers connect those who are categorized as "affected" or "emergent" to doctors. Next, doctors provide online consultations to them, referring to examined data. The doctor (based in Dhaka) subsequently diagnoses them before issuing prescriptions. Doctors consider referring those categorized as "emergent" to a higher-level health facility. Those who are classified as "caution"

receive health education from health workers. Following the WHO guideline, health checkups are conducted in the 4th, 6th, 8th, and 9th months of pregnancy and at 2–3 days, 7 days, and 6 weeks after delivery/birth from which data are collected. Several subjective symptoms are examined through an in- interview with mothers depending on the stage of pregnancy and childbirth.

What are the possible benefits and risks of participating?
Benefit is that health issues may be detected earlier than usual.
Possibility of an adverse effect on health due to health checkups. As a general rule, medical devices used in health checkups have been approved by the Japanese Pharmaceutical Affairs Law.
Possibility of side effects due to the prescribed medicine.

Where is the study run from?
Kyushu University (Japan) and Grameen Communications (Bangladesh)

When is the study starting and how long is it expected to run for?
April 2021 to March 2024

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Kimiyo Kikuchi, kikuchi.kimiyo.715@m.kyushu-u.ac.jp

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Research for maternal and child remote health checkups using ICT in Bangladesh: an intervention study

Study objectives
Remote health checkup intervention improves the continuum of care in maternal and child health.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/08/2018, and revised 20/05/2021, Institutional Review Board of the Kyushu University (3-1-1 Maidashi, Higashi-ku, Fukuoka, 812-8582, Japan; +81-92-642-5774; byskenkyu@jimu.kyushu-u.ac.jp), ref: 2020220

Study design
Interventional non-randomised

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Community

Study type(s)
Screening

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

Health condition(s) or problem(s) studied
Maternal and child health, telemedicine

Interventions
Current interventions as of 21/06/2022:

6 unions in the Shariatpur district were allocated to 2 clusters according to either the intervention or control group.

For the intervention group, we provide antenatal and postnatal checkups to pregnant and parturient women/infants using a remote health care system.
Women/infants in the control group do not receive remote health checkup, but can receive health checkups at a general health facility as usual.

Participants are selected based on the list of pregnant women that the local administration office possesses. Then, three months after the survey, the intervention will be implemented in the same two areas.

An implementation team consisting of 1 supervisor from GC, 1 local pharmacist, and 1 health lady will be formed. The team provides regular check-ups of the study participants using the portable health clinic. They conduct routine check-ups. The examined data will be sent to the doctors of the call center located in the GC. Once the examined data have been entered into the identification system, the health status will be automatically categorized into four stages (healthy, caution, affected, and emergent) following the criteria. Women categorized as “affected” and “emergent” will see the doctors through the telemedicine system. If necessary, the doctor will provide them a prescription or refer them to the nearest health facility.

Previous interventions:

9 unions in Shariatpur district were divided into 2 clusters according to the population (2 unions and 7 unions). They were randomly allocated to either the intervention or control group. Allocation was performed by generating random numbers by a computer.

For the intervention group, we provide antenatal and postnatal checkups to pregnant and parturient women/infants using a remote health care system.
Women/infants in the control group do not receive remote health checkup, but can receive health checkups at a general health facility as usual.

Participants are selected based on the list of pregnant women that the local administration office possesses. Then, three months after the survey, the intervention will be implemented in the same two areas for three years.

An implementation team consisting of 1 supervisor from GC, 1 local pharmacist, and 1 health lady will be formed. The team provides regular check-ups of the study participants using the portable health clinic. They conduct routine check-ups. The examined data will be sent to the doctors of the call center located in the GC. Once the examined data have been entered into the identification system, the health status will be automatically categorized into four stages (healthy, caution, affected, and emergent) following the criteria. Women categorized as “affected” and “emergent” will see the doctors through the telemedicine system. If necessary, the doctor will provide them a prescription or refer them to the nearest health facility.

Intervention Type
Behavioural

Primary outcome measure

Continuum of care rate measured as the percentage of participants who completed both antenatal care 4 times and more as well as postnatal care three times and more using patient records

Secondary outcome measures
Detection of perinatal complications throughout the study period measured using patient records

Overall study start date
01/04/2018

Completion date
31/03/2027

Eligibility

Key inclusion criteria
1. Pregnant women 15 - 49 years old and their infants
2. Live in Chhaygaon union

Participant type(s)
All

Age group
Mixed

Lower age limit
15 Years

Upper age limit
49 Years

Sex
Female

Target number of participants
500

Key exclusion criteria
1. Do not possess Bangladesh Nationality
2. Have a minimum health condition to receive health checkups and consultation

Date of first enrolment
01/06/2020

Date of final enrolment
01/06/2024

Locations

Countries of recruitment
Bangladesh

Study participating centre
Grameen Communications
Telecom Bhaban (Level - 7) 53/1 Box Nagar
Zoo Road
Dhaka
Bangladesh
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Kyushu University

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Sponsor type
University/education

Website
http://www.kyushu-u.ac.jp/english/

ROR
https://ror.org/00p4k0j84

Funder(s)

Funder type
Other

Funder Name

Investigator initiated and funded

Results and Publications

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

Intention to publish date
31/03/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request (kikuchi.kimiyo.715@m.kyushu-u.ac.jp)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		15/12/2022	16/12/2022	Yes	No