Using Mobile Phones to Measure Diarrhoea

Submission date 06/03/2019	Recruitment status No longer recruiting	[_] Prosp [_] Proto
Registration date 20/03/2019	Overall study status Completed	[_] Statis [X] Resul
Last Edited 02/07/2020	Condition category Infections and Infestations	[_] Individ

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- dual participant data

Plain English summary of protocol

Background and study aims

With diarrhoea being one of the two most significant causes of death in children under five, collection of accurate data on diarrhoea prevalence is of paramount importance. However, collecting this data has been proven difficult. Standard questions used to asses diarrhoea, asking if a child has had diarrhoea two or more times in the past two weeks, has been seen to suffer from recall bias, social desirability, high cost of data collection, and Hawthorne effects. To address this, we will study the impact of shortening recall period to 24 hours, including a multilevel questionnaire, and altering incentive level. We will do this while collecting data using mobile phone text messaging.

Who can participate?

Households selected will have at least one child under the age of five, live in the study area, and have access to mobile phones.

What does the study involve?

Participants will be randomised into one of eight cohorts. Each cohort, at random order, will be subjected to every possible combination of incentive (no incentive or TZS1000 incentive), recall period (two week or 24 hour), and questionnaire type (standard question or three level). Over eight two-week rounds of data collection, participants will receive surveys on diarrhoea as per their randomisation, and will be remunerated and incentivised as necessary.

What are the possible benefits and risks of participating?

Possible harms of the study surround discomfort with questions being asked, however, participants are free to withdraw at any time. Further, there is small risk of a breach of confidentiality. To address this, data is kept separately from identifiers, and all data are encrypted. There are no direct benefits, however, if a participant reports a medically concerning symptom, they will be referred to a local clinic.

Where is the study run from?

UN-Habitat Regional Office for Africa and the Arab States, Nairobi (Kenya)

When is the study starting and how long is it expected to run for? Data collection will begin in April 2019 and end in August 2019.

Who is funding the study? University of Warwick, UK

Who is the main contact? Ryan Rego (ryan.rego@warwick.ac.uk) and Samuel Watson (s.watson.1@warwick.ac.uk)

Contact information

Type(s) Scientific

Contact name Mr Ryan Rego

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Additional identifiers

EudraCT/CTIS number Nil known

IRAS number

ClinicalTrials.gov number Nil known

Secondary identifying numbers REGO2018-2148

Study information

Scientific Title Pilot testing of a parent record of child health

Acronym SMSdiarrhoea

Study objectives

This study aims to evaluate several hypothesises aimed at improving traditional diarrhoea measurement methods, asking if a child has had two or more loose or watery stool in the past two weeks. These are:

- Reducing the recall threshold from two weeks to 24 hours will decrease prevalence

- The use of a three point scale asking further questions on number of schools, treatment, and blood will result in lower prevalence than the standard measure

- That response rates vary over time

- That incentive alters response rate and data quality

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 12/01/2018, Warwick Biomedical & Scientific Research Ethics Committee (University House, University of Warwick, Coventry, CV4 7AL; E.C.Dight@warwick.ac.uk; 024 765 73961), ref: REGO-2018-2148

Study design Individual level crossover factorial randomised controlled trial

Primary study design

Observational

Secondary study design Individual level crossover factorial RCT

Study setting(s) Community

Study type(s) Screening

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

Diarrhoea/Enteric Infection

Interventions

Differing recall periods; questionnaire types; and incentive levels for diarrhoea surveys.

Initially, households will be randomised into one of eight cohorts using block randomisation. At every two week periods, cohorts will switch into new surveying strategies. These strategies are unique combinations of recall period (two week or 24 hour); questionnaire type (three level or one level); and incentive level (no incentive or some incentive). All surveys will take place by mobile phone text messaging, and all cohorts will experience all combinations of treatments at any time - through a random sequence. This study will ake place in slums around Mwanza, Tanzania.

Intervention Type

Other

Primary outcome measure

Diarrhoea Prevalence through the use of a mobile phone survey. This will take place at pre-set time points either daily or every two weeks for a period of 16 weeks.

Secondary outcome measures

Trends in diarrhoea prevalence over time

Overall study start date 01/04/2018

Completion date

01/11/2019

Eligibility

Key inclusion criteria

1. Resides in the enumeration area

- 2. Has a child under five
- 3. Has access to mobile phone
- 4. Consents to study

Participant type(s)

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Age group

Mixed

Sex

Both

Target number of participants 150

Total final enrolment 141

Key exclusion criteria

Child under five is exclusively breast fed
Does not have their own mobile phone (e.g. shares phone or no access to phone)

Date of first enrolment 15/03/2019

Date of final enrolment 01/04/2019

Locations

Countries of recruitment Kenya

Tanzania

Study participating centre UN-Habitat

UN-HABITAT Regional Office for Africa and the Arab States P.O. Box 30030, GPO Nairobi Kenya 00100

Sponsor information

Organisation University of Warwick

Sponsor details RIS, University House Coventry England United Kingdom CV4 7AL +44 (0)24 76 524760 wmsgrantssupport@warwick.ac.uk

Sponsor type University/education

Website warwick.ac.uk

ROR https://ror.org/01a77tt86

Funder(s)

Funder type University/education **Funder Name** University of Warwick

Alternative Name(s) The University of Warwick, Warwick

Funding Body Type Private sector organisation

Funding Body Subtype Universities (academic only)

Location United Kingdom

Results and Publications

Publication and dissemination plan

Conference presentation (Water and Health 2019, USA) and planned publication in a high-impact peer-reviewed journal

Intention to publish date

01/12/2019

Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	30/06/2020	30/06/2020	Yes	No