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Study on the effect of the 'talking textile' baby-wrap cloth as communication strategy for childhood vaccination coverage in Niger, West Africa

Submission date
11/07/2020

Recruitment status
No longer recruiting

Registration date
30/07/2020

Overall study status
Completed

Last Edited
19/10/2022

Condition category
Infections and Infestations

[X] 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
The wax print is a centuries-old style of printed cotton fabric that is used throughout Africa for clothing and other practical items like the baby-carrying cloth or baby-wrap. It is a cultural norm in West Africa and is sometimes used to promote health campaigns. With members from Japan, Niger, and the United States, the baby-wrap team has developed a health literacy project that deploys a factory printed baby-wrap as a 'talking textile' for childhood vaccination information to new mothers. The design of this cloth print was created in collaboration with artists and artisans in Niger. The final prototype of the symbolic calendar was determined through a series of focus groups with mothers organized by the team and local partners. The study aims to evaluate the effect of this baby-wrap as a culturally-relevant communication strategy to increase childhood vaccination uptake and coverage.

Who can participate?
Mothers who have brought a newborn baby to the health center for the baby’s first vaccination visit (BCG vaccination).

What does the study involve?
Mothers who use a health center allocated to the intervention group will receive a free vaccination calendar baby-wrap with a verbal explanation of the design delivered by a trained healthcare agent at the time of routine vaccination services.
Mothers who use a health center allocated to the control group will receive a free, plain length of cloth as a “placebo” baby-wrap that includes neither a visual design nor additional verbal explanation of the vaccination calendar at the time of routine services.

What are the possible benefits and risks of participating?
Benefits for the intervention group mothers would be that through the baby wrap the mother would understand the complex vaccination calendar or at least the time between the appointments and the number of times she must bring her child for vaccination. Risks for the

control group mothers would be that they would not acquire knowledge about the vaccination calendar and their babies might not be vaccinated for certain vaccines.

Where is the study run from?
Ministry of Public Health Niamey (Niger)

When is the study starting and how long is it expected to run for?
September 2019 to September 2021

Who is funding the study?
1. Bill & Melinda Gates Foundation (USA)
2. ZTwist Design LLC (USA)

Who is the main contact?
Ms. Mika Kondo Kunieda
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Study website
https://www.ztwist.design/niger-baby-wrap

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

KeioSFC_263_2019

Study information

Scientific Title
Promoting awareness and timely completion of childhood immunization with the Vaccination Calendar Baby-Wrap for caregivers in Niger

Study objectives
The free provision of the baby-wrap with a culturally-relevant design will increase vaccination coverage rates among children and promote maternal knowledge of the recommended vaccination calendar.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 18/11/2019, Niger Ethics Review (Comité National d'Éthique pour la Recherche en Santé CNERS, s/c République du Niger Ministère de la Santé Publique Direction des Etudes et de la Programmation BP 623 Niamey, Niger; no telephone number provided; no email provided), ref: 44/2019/CNERS
2. Approved 02/12/2019, Keio University SFC Ethics Committee for Experimentation and Examination (c/o Keio University Shonan Fujisawa Campus, 5322 Endo Fujisawa, Kanagawa, Japan; no telephone number provided; somu@sfc.keio.ac.jp), ref: approval 263

Study design
Interventional stratified randomized control trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Prevention

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
Vaccination coverage (for BCG, Pentavalent 1, Pentavalent 3 and measles vaccines)

Interventions
This intervention study will be conducted in two phases:
Phase One

Collect and analyze updated administrative data from the EPI and vaccination coverage data in order to pair health centers in Niamey and allocate them to the intervention and control groups for the randomized control trial (RCT). Health center selection methodology is described in Annex 1. Healthcare personnel at both the intervention and control health centers will receive training on interpersonal communication by local partners in the public health sector. Healthcare personnel at the intervention clinics will be trained to deliver an explanation of the vaccination calendar baby-wrap design to mothers.

Phase Two
A survey of mothers who bring their newborn infants to the first vaccination appointment at either an intervention or control health center will acquire basic socio-demographic information and assess baseline understanding of vaccination appointments and vaccine-seeking behaviors. The study includes an explanation of the survey and expectations from participants. Mothers interested in participating will give their informed consent through a signature or a thumbprint.

Mothers who use a health center allocated to the intervention group will receive a free vaccination calendar baby-wrap with a verbal explanation of the design delivered by a trained healthcare agent at the time of routine vaccination services. Mothers who use a health center allocated to the control group will receive a free, plain length of cloth as a 'placebo' baby-wrap that includes neither a visual design nor additional verbal explanation of the vaccination calendar at the time of routine services.

All mothers with infants receiving the first vaccination at both control and intervention health centers will receive the free baby-wraps during a time-limited distribution period to avoid perceptions of unfairness or adverse negative effects associated with perceptions of unfairness. The DRSP Niamey will be responsible for the distribution of both the placebo and vaccination calendar baby-wraps according to the terms set out in this protocol.

The surveyed mothers and their infants from both the intervention and control clinics will be monitored for ten months to determine if they have completed the first five visits of the vaccination series, specifically whether they have received BCG at their first visit, Penta 1 at their second visit, Penta 3 at their fourth visit, and measles vaccine at their fifth visit.

The Baseline Survey will be administered at the first visit of the mother and child. The Post-Intervention Survey on motivation, ability, and prompts to vaccinate will be administered at the fourth visit when the child is 3 months old. The Post-Intervention Survey will be administered a second time at the fifth visit when the mother comes in for measles vaccine for her 9-month-old child, in order to assess any changes in vaccination knowledge and behavior from the first and second surveys.

To address potential perceptions of unfairness or spillover effect between mothers who received the vaccination calendar baby-wrap and those mothers who received the placebo baby-wrap, the selected intervention clinics and the control clinics will be geographically distant so that information will travel slowly, if at all. Mothers will only qualify to receive a baby-wrap if their child is receiving BCG during the fixed distribution period and will not receive more than one baby-wrap.

The mothers in the control group will be administered the same surveys as mothers in the intervention group. If mothers in either the control or intervention group do not come back for subsequent vaccination appointments, they will be contacted a full month after the missed vaccination date for a phone interview using the same questionnaire used for women who received the survey in person. The goal of the phone interview will be to determine if women

who dropped out experienced increased barriers that prevented them from returning for vaccination. It is expected that the phone interview will prompt mothers to re-engage with the health system, therefore, data from any subsequent vaccinations will be tracked separately from participants who were interviewed in person at the health clinics.

Follow-up of participants will be for 10 months.

Intervention Type
Behavioural

Primary outcome measure
Vaccination coverage of children measured using patient records at 9 months

Secondary outcome measures
Maternal knowledge of the recommended vaccination calendar at baseline and follow up (9 months) using the Fogg behavioral model questionnaire on motivation

Overall study start date
01/09/2019

Completion date
30/09/2021

Eligibility

Key inclusion criteria
1. Mothers with newborn infants residing in Niamey, Niger
2. The mother has brought a newborn baby to the health center for the baby's first vaccination visit (BCG vaccination)
3. The parents/mother have/has given their/her consent by signature or thumbprint, to being interviewed three times during the study period, after being informed of the survey

Participant type(s)
Mixed

Age group
Adult

Sex
Female

Target number of participants
1,000

Total final enrolment
1697

Key exclusion criteria

1. Those persons who do not consent to be interviewed
2. Those mothers and newborns who do not intend to stay in Niamey during the study period (approximately ten months)

Date of first enrolment
01/10/2020

Date of final enrolment
31/10/2020

Locations

Countries of recruitment
Niger

Study participating centre
Ministry of Public Health Niamey
Niamey
Niger
-

Sponsor information

Organisation
ZTwist Design LLC

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Sponsor type
Other

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Funder(s)

Funder type
Charity

Funder Name
Bill and Melinda Gates Foundation

Alternative Name(s)
Bill & Melinda Gates Foundation, Gates Foundation, BMGF, B&MGF, GF

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Results and Publications

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

Intention to publish date
31/12/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			19/10/2022	No	No