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Oral health intervention for improving overall health status of children living with HIV in Cambodia

Submission date
15/12/2017

Recruitment status
No longer recruiting

Registration date
17/01/2018

Overall study status
Completed

Last Edited
12/03/2025

Condition category
Oral Health

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Worldwide, antiretroviral therapy (ART) has dramatically improved the mortality (death rate) of perinatally HIV-infected children. The perinatally HIV-infected children treated with ART have now reached adolescence. However, promoting high ART adherence in children is difficult due to various factors. Among HIV-uninfected children, serious dental caries (cavities) may cause eating disorders or infectious diseases. This may increase the risk of malnutrition, developmental delay or lower quality of life. If the same relationship exists among children living with HIV, oral care might help to maintain their health. However, it is unclear whether oral health status is related to the overall health including infectious diseases, or the development of children living with HIV. Cambodia has achieved success in reducing new HIV infections. However, the prevalence is rather high among South-Asian countries. Additionally, oral health is a critical issue to be tackled among children in Cambodia. The aim of this study is to assess the effectiveness of an oral health intervention at improving overall health status among children living with HIV in Cambodia.

Who can participate?
Children 3-15 years old living with HIV and treated with antiretroviral therapy for at least three months, HIV-negative children, and their caregivers

What does the study involve?
Participants are allocated into three groups: the intervention group (group A) and two control groups (group B and C). Group A and B include children living with HIV and their caregivers. Group C includes HIV-negative children and their caregivers. The intervention group receives an intervention for two years from May 2018 to April 2020. The interventions include oral health education sessions and daily oral care. Children and caregivers in the intervention group see research monitoring assistants at the hospital every three months following the education sessions. There are no interventions for the control groups. The impact of the intervention is assessed by comparing children in the intervention and the control groups, and by assessing the changes in the intervention groups at the start, middle and end of the study.

What are the possible benefits and risks of participating?
Participants benefit from improved oral health knowledge and behaviours. The intervention will be introduced to the control group participants immediately if it is found to have a positive impact. Hospitals are encouraged to refer if they identify minor, acute, or chronic illness in children in either the intervention or control groups. The intervention is not invasive, so the participants are not exposed to marked risks.

Where is the study run from?
National Pediatric Hospital (Cambodia)

When is the study starting and how long is it expected to run for?
January 2018 to March 2022

Who is funding the study?
Japan Society for the Promotion of Science (Japan)

Who is the main contact?
1. Dr Kimiyo Kikuchi (public)
2. Dr Yi Siyan (scientific)

Contact information

Type(s)
Public

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Type(s)
Scientific

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3

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1.0

Study information

Scientific Title
Oral health intervention for improving overall health status of children living with HIV in Cambodia: a randomized controlled trial

Study objectives
How will the oral health intervention influence the overall health status of children living with HIV?

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Ethics Committee for Health Research, Cambodia - approval pending

Study design
Multicentre randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Other

Study type(s)
Prevention

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
Oral health in children with HIV infection

Interventions
The intervention group and two control groups will be allocated in a 1:1:1 ratio. By the nature of the study, participants and care providers will not be masked. Randomization scheme generated via a computerized algorithm will be used to assign participants to study arms. Although randomization is not blinded, recruiters will not be aware of group allocation until after

participants have completed the baseline assessment. Information on group assignments will be provided to the recruiters in sealed envelopes.

An intervention study will be conducted in Phnom Penh, Cambodia. The intervention effectiveness will be evaluated by comparing data collected at baseline, mid-term (a year after implementing the intervention) and endline. The study participants will be included in three arms: the intervention arm (group A) and two control arms (group B and C). Targets of group A and B will include children living with HIV and their caregivers. Targets of group C will be HIV-negative children and their caregivers. For groups A and B, children will be included in the study if they are in the age group of 3 to 15 years and under ART for at least three months. For group C, children will be included in the study if they are aged 3 to 15 years old and HIV-negative. Sample size of each arm has been set in a total of 260 dyads of a child and a caregiver. The minimum required number of dyads in the three arms would be 780.

Target children and caregivers will receive an intervention for two years from May 2018 to April 2020. The main components of the intervention will include oral health education sessions and being recommended to practice daily oral care. Children and caregivers in the intervention arm will see research monitoring assistants at the hospital every three months following the education sessions. There will be no intervention for the control groups.

The impact of the intervention will be assessed by comparing key outcome indicators among children in the intervention and the control arms, as well as by metachronic changes of the intervention arms. The comparison between arms will be performed by measuring outcome indicators at baseline, mid-term and endline.

Baseline: January 2018
Mid-term: April 2019
Endline: April 2020
Follow-up tests: every three months.

Updated 01/03/2021:
Baseline: January 2018
Mid-term: April 2019
Endline: January 2021
Follow-up tests: every three months.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measure as of 01/03/2021:
1. Oral health status (decayed, missing, filled permanent teeth), assessed by dental check by dentist at baseline, mid-term, and endline survey
2. Viral load, CD4 count, measured by blood examination in the routine care of people living with HIV every 3 months

Previous primary outcome measure:
1. Oral health status (decayed, missing, filled permanent teeth), assessed by dental check by dentist at baseline, mid-term, and endline survey
2. CD4 count, measured by blood examination in the routine care of people living with HIV every 3 months

Secondary outcome measures
1. Saliva buffer capacity, measured by examining collected saliva by rapid test kit (CAT21buf) at baseline, mid-term, and endline survey
2. Number of cariogenic bacteria, measured by examining collected saliva by rapid test kit (Cariscreen) every 3 months
3. Debris index score, measured by staining plaque with staining liquid for teeth every 3 months
4. Saliva secretion capacity: measured by examining collected saliva by rapid test kit (CAT21buf) at baseline, mid-term, and endline survey
5. Nutrition status, measured by measuring height and weight at baseline, mid-term, and endline survey
6. Quality of life, measured using Pediatric Quality of Life Inventory (version 4.0) every 3 months

Overall study start date
04/01/2018

Completion date
31/03/2022

Eligibility

Key inclusion criteria
1. Children living with HIV: 3-15 years old, under antiretroviral therapy for at least three months
2. HIV-negative children: 3-15 years old, HIV negative
3. Caregiver: 18 or above, child's primary caregiver

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
a) Intervention group: HIV positive children and caregivers: 260 dyads, b) Control group: HIV positive children and caregivers: 260 dyads, c) Control group: HIV negative children and caregivers: 260 dyads

Total final enrolment
480

Key exclusion criteria
Mentally or physically too sick to participate in the study

Date of first enrolment
01/02/2018

Date of final enrolment
31/03/2020

Locations

Countries of recruitment
Cambodia

Study participating centre
National Pediatric Hospital
100 Russian Federation Boulevard
Phnom Penh
Cambodia
N/A

Sponsor information

Organisation
Institute of Decision Science for a Sustainable Society, Kyushu University

Sponsor details
744 Motooka, Nishi-ku
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819-0395

Sponsor type
University/education

ROR
https://ror.org/00p4k0j84

Funder(s)

Funder type
Research organisation

Funder Name
Japan Society for the Promotion of Science

Alternative Name(s)
KAKENHI, , Gakushin, JSPS KAKEN, JSPS Grants-in-Aid for Scientific Research, JSPS

Funding Body Type

Government organisation

Funding Body Subtype
National government

Location
Japan

Results and Publications

Publication and dissemination plan
Protocol will be submitted to the journal before the intervention study. Other study findings will be published in a high-impact peer reviewed journal at one year after the overall trial end date.

Intention to publish date
31/03/2022

Individual participant data (IPD) sharing plan
The participant level data will not be expected to be made available because the data contains personal information of people living with HIV including sero-status of participants and their family.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	06/12/2018		Yes	No
Results article		28/04/2023	02/05/2023	Yes	No
Other publications	Baseline survey	25/03/2021	12/03/2025	Yes	No