

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

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| <b>Submission date</b><br>15/12/2017   | <b>Recruitment status</b><br>No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol |
| <b>Registration date</b><br>17/01/2018 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results            |
| <b>Last Edited</b><br>12/03/2025       | <b>Condition category</b><br>Oral Health          | <input type="checkbox"/> 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

### Contact name

Dr Kimiyo Kikuchi

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### Type(s)

Scientific

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## Additional identifiers

Protocol serial number

## 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

### Study type(s)

Prevention

### 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(s)**

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

## **Key secondary outcome(s)**

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

## **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

### Healthy volunteers allowed

No

### Age group

Mixed

### Sex

All

### 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

ROR

<https://ror.org/00p4k0j84>

## Funder(s)

### Funder type

Research organisation

### Funder Name

Japan Society for the Promotion of Science

### Alternative Name(s)

KAKENHI, JSPS KAKEN, JSPS Grants-in-Aid for Scientific Research, Gakushin, , Nihon Gakujutsu Shinkō Kai, JSPS

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

Japan

## Results and Publications

### 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? |
|---|-------------------------------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>               |                               | 28/04/2023   | 02/05/2023 | Yes            | No              |
| <a href="#">Protocol article</a>              | protocol                      | 06/12/2018   |            | Yes            | No              |
| <a href="#">Other publications</a>            | Baseline survey               | 25/03/2021   | 12/03/2025 | Yes            | No              |
| <a href="#">Participant information sheet</a> | Participant information sheet | 11/11/2025   | 11/11/2025 | No             | Yes             |