ISRCTN86890686 https://doi.org/10.1186/ISRCTN86890686

# Using light therapy at home to improve dental hygiene: a study on healthy adults

**Submission date**
13/03/2025

**Recruitment status**
No longer recruiting

**Registration date**
28/03/2025

**Overall study status**
Completed

**Last Edited**
14/03/2025

**Condition category**
Oral Health

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

## Plain English summary of protocol

Background and study aims
Toothbrushing, whether with an electric or manual toothbrush, often leaves 35–50% of plaque behind. Regular use of antibacterial photodynamic therapy has emerged as a promising method to enhance oral hygiene at home. This study aims to evaluate the effectiveness of the antibacterial Lumoral® light-activated treatment in reducing dental plaque as part of daily dental care in healthy volunteers.

Who can participate?
Healthy adults who do not have fixed orthodontic appliances, fixed partial dentures, advanced periodontitis, significant pathology in the oral cavity, or restorable caries lesions. Participants should not have used antibiotics within the last month, should not smoke, and should not have had recent professional dental cleaning or participated in other oral health examinations.

What does the study involve?
Participants will be randomly assigned to one of two groups. One group will receive oral hygiene instructions and use Lumoral® as an additional plaque control method twice a week. The other group will receive oral hygiene instructions alone. Dental plaque will be measured at the start and after four weeks using the Rustogi-modified Navy Plaque Index. Researchers who do not know which group participants are in will conduct the measurements.

What are the possible benefits and risks of participating?
Participants may benefit from improved dental hygiene and reduced plaque levels. Risks are minimal but may include mild discomfort from using the Lumoral® device.

Where is the study run from?
Koite Health Ltd. (Finland)

When is the study starting and how long is it expected to run for?
August 2022 to March 2023

Who is funding the study?
The study was performed in collaboration with the Metropolia University of Applied Sciences

and Koite Health Ltd.
Koite Health Ltd. provided the investigational devices for the study. No direct financial contributions to the researchers or the study center were made.

Who is the main contact?
Mikko Kylmänen, mikko.kylmanen@koitehealth.com

# Contact information

### Type(s)
Public


### Contact name
Mr Mikko Kylmänen

### Contact details
Karaportti 5
Espoo
Finland
02610
+358 407245934
mikko.kylmanen@koitehealth.com

### Type(s)
Scientific

### Contact name
Dr Tommi Pätilä

### ORCID ID
https://orcid.org/0000-0003-2219-4689

### Contact details
Stenbäckinkatu 9
Helsinki
Finland
00290
+358 440130770
tommi.patila@gmail.com

### Type(s)
Principal investigator

### Contact name
Ms Saila Pakarinen

### Contact details
Myllypurontie 1
Helsinki
Finland

00790
+358 75167956
pakarinen.saila@metropolia.fi

# Additional identifiers

# Study information

### Scientific Title
Regularly home-applied dual-light photodynamic therapy on dental hygiene- a prospective randomized study in healthy adults

### Acronym
SHINE

### Study objectives
The Lumoral® treatment, when used twice a week as an adjunct to regular oral care, improves oral hygiene in healthy individuals.

### Ethics approval required
Ethics approval required

### Ethics approval(s)
Approved 31/01/2023, The Human Sciences Ethics Committee of the Helsinki Region Universities of Applied Sciences (Myllypurontie 1, Helsinki, 00920, Finland; +358 401937758; eettinen.toimikunta@metropolia.fi), ref: § 8/2023

### Primary study design
Interventional

### Study design
Interventional randomized controlled trial

### Study type(s)
Efficacy

### Health condition(s) or problem(s) studied
Dental plaque

### Interventions
At baseline and at 4-week follow-up (+/- 1 week), the biofilm of the subjects' mouths is stained using plaque dye, and clinical plaque index measurements is obtained.

After the baseline visit, study subjects are given comprehensive oral self-care instructions including mechanical biofilm removal from free tooth surfaces and interdental spaces.

Those randomized in the Treatment group are given a Lumoral® Treatment device and thorough verbal and written instructions to perform dual-light aPDT at home in addition to the comprehensive oral self-care instructions.

The participants are randomly assigned to the test and control groups using a sealed envelope technique.

### Intervention Type
Device

### Phase
Not Applicable

### Drug/device/biological/vaccine name(s)
Lumoral

### Primary outcome(s)
Dental plaque levels measured using the Rustogi-modified Navy Plaque Index from clinical plaque staining and scoring at Baseline and Week 4 (+/-1 week)

### Key secondary outcome(s)
Subjective experience of using the Lumoral® Treatment device measured using a structured questionnaire at Week 4 (+/-1 week)

### Completion date
31/03/2023

## Eligibility

### Key inclusion criteria
Subjects had to be from 18 to 70 years' age and good general health assessed by study participants themselves.

### Participant type(s)
Healthy volunteer

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 Years

### Upper age limit
70 Years

### Sex
All

### Total final enrolment
15

### Key exclusion criteria
1. Oral health-related issues, including fixed orthodontic appliances, fixed partial dentures, advanced periodontitis, significant pathology in the oral cavity, or restorable caries lesions.
2. Medication-related issues, including use of antibiotics within one month.
3. Other factors, including smoking, participation in other oral health examinations, and recent professional dental cleaning.

### Date of first enrolment
15/02/2023

### Date of final enrolment
03/03/2023

## Locations

### Countries of recruitment
Finland

### Study participating centre
**Metropolia University of Applied Sciences, Myllypuro Campus**
Myllypurontie 1
Helsinki
Finland
00920

## Sponsor information

### Organisation
Koite Health Ltd.

## Funder(s)

### Funder type
Industry

### Funder Name
Koite Health Ltd.

## Results and Publications

## Individual participant data (IPD) sharing plan
No plan to share IPD.

## IPD sharing plan summary
Not expected to be made available