

# A survey investigating health-related quality of life in adolescents with moyamoya disease

<b>Submission date</b> 09/12/2021	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 09/12/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 20/12/2021	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Moyamoya disease is a chronic (long-term) progressive (that gets worse with time) disease of the blood vessels of the brain (cerebrovascular) that requires regular monitoring to control the disease and its related complications. Moyamoya disease can lead to stroke or bleeding in the brain or stroke. It can also affect brain function and cause disability.

This study aims to investigate whether understanding of the disease, a sense of coherence and social support were significant factors contributing to lower stress, improved health, and quality of life in adolescents with moyamoya disease. This study aims to help health experts to develop a treatment strategy based on a health and wellbeing approach for chronic disease management.

### Who can participate?

Adolescents who have had moyamoya disease for longer than one month with no other diseases.

### What does the study involve?

Participants will complete questionnaires about social support, sense of coherence, stress, health behavior, health status, and quality of life on a single occasion.

### What are the possible benefits and risks of participating?

The potential benefits to participants are that they might better understand the factors affecting their health-related quality of life with moyamoya disease and other chronic diseases. There are no anticipated risks as this study is a survey.

### Where is the study run from?

Yonsei University (Korea, South)

### When is the study starting and how long is it expected to run for?

From November 2017 to October 2018

### Who is funding the study?

National Research Foundation of Korea (NRF) (Korea, South)

Who is the main contact?

Prof Insun Yeom  
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## Contact information

### Type(s)

Public

### Contact name

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

SHAM123, NRF-2019R1AC1004633

## Study information

### Scientific Title

Structural equation model of health-related quality of life in adolescents with moyamoya disease: based on the salutogenesis theory

### Study objectives

Knowledge of moyamoya disease, social support, and sense of coherence affect individual stress and health behaviors, in turn affecting subjective health status, depression, and quality of life

### Ethics approval required

Old ethics approval format

**Ethics approval(s)**

Approved 11/07/2017, Severance Hospital Institutional Review Board (Yonsei University Health System, 50-1 Yeonse-ro, Seodaemun-gu, Seoul 03722, Korea; +82-02-2228-0450; irb@yuhs.ac)

**Study design**

Cross sectional study

**Primary study design**

Observational

**Secondary study design**

Cross sectional study

**Study setting(s)**

Hospital

**Study type(s)**

Not Specified

**Participant information sheet**

No participant information sheet available

**Health condition(s) or problem(s) studied**

Adolescents with Moyamoya disease

**Interventions**

The study involves a cross-sectional survey of Korean adolescents with Moyamoya disease. The study will examine a hypothetical model by integrating the concepts of a structural health-related quality-of-life model based on the salutogenesis theory among adolescents with moyamoya disease in Korea. Data on health-related quality of life of adolescents with moyamoya disease will be collected at a single timepoint using the following scales: social support rating scale, sense of coherence scale, stress scale, health behavior scale, subjective health status scale, and quality-of-life scale. A structural equation model will be used to analyze the data.

**Intervention Type**

Other

**Primary outcome measure**

1. Subjective health status measured using a 5-point simple-question Likert scale, ranging from 1 point (very bad) to 5 points (very good) at a single timepoint
2. Quality of life measured using a quality of life scale (Varni et al., 1998) at a single timepoint

**Secondary outcome measures**

1. Social support measured using a social support scale (Malecki et al., 2000) at a single timepoint. Higher scores indicate more social support in each area.
2. Sense of coherence measured using a sense of coherence scale (Antonovsky, 1987) at a single timepoint
3. Health behavior measured using the moyamoya health behavior scale (Oh et al., 2021) at a

single timepoint. Higher scores indicate better health behaviors related to moyamoya disease.  
4. Stress measured using the stress scale for adolescents (Kim and Bae, 2014) at a single timepoint

**Overall study start date**

01/11/2017

**Completion date**

30/10/2018

## Eligibility

**Key inclusion criteria**

1. Moyamoya disease for >1 month
2. No other diseases
3. Able to respond to a questionnaire.
4. Able to confirm their understanding of the purpose of the study and agree to participate voluntarily providing online written consent
5. Aged between 13 and 18 years

**Participant type(s)**

Patient

**Age group**

Mixed

**Sex**

Both

**Target number of participants**

230

**Total final enrolment**

239

**Key exclusion criteria**

1. History of mental illness
2. Difficulty in participating (e.g. hearing and visual impairment)

**Date of first enrolment**

01/01/2018

**Date of final enrolment**

30/10/2018

## Locations

**Countries of recruitment**

Korea, South

**Study participating centre****Yonsei University**

Moyamoya Disease Clinic

Pediatric Neurosurgery

50-1 Yonse-ro

Seodaemun-gu

Seoul

Korea, South

03722

**Sponsor information****Organisation**

Yonsei University

**Sponsor details**

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**Sponsor type**

University/education

**Website**

<http://www.yonsei.ac.kr/eng/>

**ROR**

<https://ror.org/01wjejq96>

**Funder(s)****Funder type**

Government

**Funder Name**

National Research Foundation of Korea

**Alternative Name(s)**

, National Research Foundation (South Korea), NRF

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

Korea, South

## Results and Publications

**Publication and dissemination plan**

Planned publication in an open-access journal.

**Intention to publish date**

01/01/2022

**Individual participant data (IPD) sharing plan**

Data will be made available upon request to Prof Won-oak Oh (wooh@korea.ac.kr)

**IPD sharing plan summary**

Available on request