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

Submission date	Recruitment status	Prospectively registered
09/12/2021	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
09/12/2021	Completed	Results
Last Edited	Condition category	Individual participant data
20/12/2021	Circulatory System	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 ruthin76@yuhs.ac

# Contact information

# Type(s)

Public

#### Contact name

Prof Insun Yeom

#### **ORCID ID**

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# Additional identifiers

## Clinical Trials Information System (CTIS)

Nil known

## ClinicalTrials.gov (NCT)

Nil known

#### Protocol serial number

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

#### Study type(s)

**Not Specified** 

#### 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(s)

- 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

# Key secondary outcome(s))

- 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

# 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** 

#### Healthy volunteers allowed

No

#### Age group

Mixed

#### Sex

All

#### 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 Yeonse-ro Seodaemun-gu Seoul Korea, South 03722

# Sponsor information

#### Organisation

Yonsei University

#### **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**

## 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

## **Study outputs**

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet

Participant information sheet 11/11/2025 11/11/2025 No