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

Submission date
09/12/2021

Registration date
09/12/2021

Last Edited
20/12/2021

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Circulatory System

☐ Prospectively registered
☐ Protocol
☐ Statistical analysis plan
☐ Results
☐ Individual participant data
☐ 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
https://orcid.org/0000-0001-9914-9486

Contact details
Jeunggaro 150
Seoul
Korea, South
03670
+82-10-9018-5666
ruthin76@yuhs.ac

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	Yes