

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

Submission date 09/12/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 09/12/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 20/12/2021	Condition category 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 Yeonse-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