

Comprehensive program to enhance the quality of life of elderly people in nursing homes

Submission date 23/05/2022	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 08/06/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 31/10/2023	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Measuring the quality of life of the elderly is an important issue in national development planning. This can be used as a reference to determine how much budget is going to be allocated to health services and social care. In addition, this also can be used as an indicator to assess the development of the physical and mental health of the elderly. Elderly people who live in nursing homes usually have a low quality of life than those who live in the community. This is due to the high number of some incidents such as high blood pressure, falls, anxiety, diabetes, dementia, depression, and the neglect which occurs in some aspects of elderly life such as the psychological, physical, financial, and sexual aspects. Several efforts have been done to improve the quality of life of the elderly. However, these activities are focused only on one aspect of some domains of quality of life. In addition to this, the majority of the programs are implemented in the community while programs in nursing homes are relatively few. The comprehensive intervention of this study, which includes physical, mental, and spiritual aspects, makes this study different from the previous studies on the same topic. The main aim of this study is to assess the effect of the comprehensive intervention (SPIRIT) on the quality of life of elderly people in nursing homes. The other variables such as physical fitness, anxiety, blood pressure, and risk of falls are several additional measurements that will also be obtained from this study.

Who can participate?

Elderly people aged 60 years and over who have lived in a nursing home for a minimum of 3 months

What does the study involve?

Participants involved in the intervention group will be asked to perform moderate-intensity physical activity including aerobic exercise, static cycling, or walking, which is done alternately, with additional activities such as flexibility, strength, balance, breathing relaxation, and gratitude. This intervention will take 50-60 minutes and will be performed three times a week for 16 weeks accompanied by an instructor (an undergraduate student of Faculty of Sport, University of Sebelas Maret, Surakarta, Indonesia). The control group will undergo routine activities which are usually done in nursing homes. Measurements will be taken for both groups at the start of the study and after 16 weeks.

What are the possible benefits and risks of participating?

Programs based on physical, mental, and spiritual activity have been widely reported to give benefits to the elderly. This kind of program can be used to prevent non-communicable diseases and depression, and to improve quality of life. This intervention program is compiled based on previous studies. Moreover, it has been examined and received approval from sports experts and psychologists from the University of Sebelas Maret. Therefore, it is feasible to be implemented for the elderly. To minimize the risk of injury, this program will be started according to ability, starting from 40% of the maximum target pulse rate, then it can be increased gradually every 2 weeks. The instructor will monitor the pulse by using pulse oximetry during exercise and will also give an opportunity to take a rest and drink enough water. The participants can also stop doing the program at any time they wish. Caregivers will observe the health condition of participants and will communicate to the researcher.

Where the study runs for

Nursing homes in Surakarta (Indonesia)

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

July 2021 to October 2022.

Who is funding the study?

Institution of Research and Community Services, University of Sebelas Maret, Surakarta (Indonesia)

Who is the main contact?

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Contact information

Type(s)

Public

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

The effect of the SPIRIT program on the quality of life of elderly people in nursing homes

Acronym

SPIRIT

Study objectives

1. The SPIRIT program (physical exercise, static cycling, walking, respiratory relaxation, gratitude, blood pressure monitoring) is more effective at improving quality of life than the routine programs that are commonly undertaken by elderly people in nursing homes.
2. The SPIRIT program (physical exercise, static cycling, walking, respiratory relaxation, gratitude, blood pressure monitoring) is more effective at improving physical fitness than the routine programs that are commonly undertaken by elderly people in nursing homes
3. The SPIRIT program (physical exercise, static cycling, walking, respiratory relaxation, gratitude, blood pressure monitoring) is more effective at reducing anxiety than the routine programs that are commonly undertaken by elderly people in nursing homes
4. The SPIRIT program (physical exercise, static cycling, walking, respiratory relaxation, gratitude, blood pressure monitoring) is more effective at reducing blood pressure than the routine programs that commonly undertaken by elderly people in nursing homes
5. The SPIRIT program (physical exercise, static cycling, walking, respiratory relaxation, gratitude, blood pressure monitoring) is more effective at reducing the risk of falls than the routine programs that are commonly undertaken by elderly people in nursing homes

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 15/09/2021, Research Ethics Committee of Faculty of Medicine, University of Sebelas Maret (Gedung Pendidikan Dokter Baru, 2nd Floor, Faculty of Medicine, University of Sebelas Maret, Ir. Sutami Street 36 A, Surakarta, Jawa Tengah 57126, Indonesia; +62 (0)271 664178 Ext. 1125; kepk@fk.uns.ac.id), ref: 88/UN27.06.6.1/KEP/EC/2021

Study design

Double-blind cluster randomized controlled trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Community

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please contact erindrabudi@staff.uns.ac.id

Health condition(s) or problem(s) studied

Elderly people in good health

Interventions

Five nursing homes will be involved in this study. One nursing home will be assigned for a pilot study to identify the feasibility of the intervention and to measure variables. There are four nursing homes involved in the main study. The placement of respondents will be done by using cluster randomization. The cluster in this study is the nursing home. The placement of clusters to the intervention group or control group will be carried out online at <http://bagikelompok.rf.gd/?i=1>. Blinding is then performed. All participants involved in this study (administrator, data collector) do not know whether clusters are in the interventional group or the control group.

SPIRIT is a program to improve the quality of life of the elderly in nursing homes which consists of varied moderate-intensity physical activities including aerobic exercise in the form of gymnastics, static cycling, or walking, which are carried out alternately, plus flexibility, strength, balance, and other activities. breathing relaxation, and gratitude, carried out three times a week for 16 weeks accompanied by an instructor (sports and psychology expert from Sebelas Maret University, Surakarta).

The training procedure is as follows:

1. The exercise begins with a prayer together
2. A brief explanation from the instructor about the exercise
3. Physical exercise is done together in small groups
4. Warm-up movement for 5 minutes
5. Physical exercise, consisting of:
 - 5.1. Aerobic exercise, including static cycling, walking, and elderly gymnastics, selected alternately.
 - 5.1.1. Static bicycles: two 10-minute stationary cycles, with 3-minute breaks in the shade in a nursing home.
 - 5.1.2. Walking: walking in place or walking at the usual pace in the courtyard of the nursing home complex for two periods of 10 minutes with 3 minutes of rest interspersed
 - 5.1.3. Heart healthy elderly aerobic exercise. This gymnastics already includes aerobic, strength, balance, and flexibility exercises.
 - 5.2. Strength training: eight repetitions of two sets, with 1-minute rest for each set.
 - 5.3. Balance exercises: two types of balance exercises, interspersed with 1-minute rest.
 - 5.4. Flexibility exercises: three-joint flexibility exercises, eight repetitions of two sets.
6. During the exercise, the instructor asks whether the subject had any complaints such as dizziness, chest pain, shortness of breath, or movement disorders during physical exercise. If there are complaints, physical exercise is stopped. The instructor also gave words of humor and encouragement in between physical exercises.
7. Measuring the pulse using a pulse oximeter in random subjects during exercise.
8. Cool down for 5 minutes

9. Give a chance to drink at rest

10. The instructor invites the subject to sit in the shade, and leads a breathing relaxation for 5 minutes.

11. The instructor guides gratitude therapy by showing inspiring pictures or short stories, or tangible evidence of God's gifts that have been bestowed, such as food, drink, oxygen, health, etc, followed by asking the subject to name the various gifts from God that have been bestowed and inquiring about the perceived impact (whether it is closer to what it is desired, and further away from what is being worried about).

12. The instructor provides reinforcement to increase the subject's self-confidence, efficacy, and self-esteem so that they follow the program the next day and carry out the SPIRIT program independently.

13. Closing prayer.

Physical exercise equipment is provided by the researcher.

Practice principle

The SPIRIT program will be held for 16 weeks, three times a week, 50-60 minutes for each session in the morning. Physical exercise in the SPIRIT program starts according to the capability of the elderly for example 40% of the maximum pulse rate. For those participants who are fully capable to do the intervention, the program will be gradually increased in term of time, load, and will be repeated every 2 weeks until it reaches the level of recommended exercise by experts which is 150-300 minutes per week or 60-80% of the maximum pulse rate. Other exercises which include muscle strength, balance and flexibility exercises will be added one type of exercise every month. The exercises will be performed in a good emotional environment. Gratitude therapy will be started by mentioning at minimum of three gifts received from God. It is then gradually increased in number each week.

Control group

Subjects in the control group will perform normal activities as usual. Based on the data obtained by researcher, caregivers in the nursing homes allow elderly people to do their individual physical and spiritual activities independently. It is not frequent for elderly people to do activities together with others, sometimes in a week or on a certain occasion only.

Intervention Type

Behavioural

Primary outcome measure

Quality of life measured by WHO QoL BREF Bahasa Indonesia version before the intervention and after 16 weeks

Secondary outcome measures

1. Physical fitness measured using 2-minute step test at baseline and 16 weeks
2. Anxiety measured using the Beck Anxiety Inventory at baseline and 16 weeks
3. Ambulatory blood pressure measured using an automatic arm style electronic blood pressure monitor at baseline and 16 weeks
4. Risk of fall measured using the Berg Balance Scale Test at baseline and 16 weeks

Overall study start date

01/07/2021

Completion date

30/10/2022

Eligibility

Key inclusion criteria

1. ≥60 years old
2. Able to communicate
3. Willing to undergo the intervention of this study
4. Has lived in nursing homes for a minimum of 3 months
5. Has scored A on the Katz index of activities of daily living
6. Receive permission from the Director of the nursing home

Participant type(s)

Healthy volunteer

Age group

Senior

Sex

Both

Target number of participants

52

Key exclusion criteria

1. Chronic diseases which cause participants not to be able to participate in the SPIRIT program
2. Vision and hearing impairment
3. Blood pressure >180/100 mmHg
4. Oxygen saturation level <95%

Date of first enrolment

10/06/2022

Date of final enrolment

20/06/2022

Locations

Countries of recruitment

Indonesia

Study participating centre

Panti Jompo Aisyiyah Surakarta
Pajajaran Utara III Street Number 7
Surakarta
Indonesia
57138

Study participating centre**Panti Wreda Dharma Bhakti**

Dr. Rajiman street Number 620, Pajang
Surakarta
Indonesia
57146

Study participating centre**Panti Wreda Dharma Bhakti Kasih**

Kalingga Utara VI street, Kadipiro, Banjarsari
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57136

Study participating centre**Griya PMI Peduli**

Sumbing Raya Street Number 6, Mojosongo, Jebres
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57127

Sponsor information

Organisation

Sebelas Maret University

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Sponsor type

University/education

Website

<https://pasca.uns.ac.id/s3ikm/>

ROR

<https://ror.org/021hq5q33>

Funder(s)

Funder type

University/education

Funder Name

Universitas Sebelas Maret

Alternative Name(s)

Sebelas Maret University, UNS

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

Indonesia

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal

Intention to publish date

31/12/2023

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			06/06/2022	No	Yes
Basic results			31/10/2023	No	No